



**ISO NUCLEAR QUALITY ASSURANCE
MANUAL**

For The design, development, production, installation and repair of nuclear and conventional pressure vessels as well as welded structures (such as internals, spent fuel cells, racks and containers); up-grading and certification of base materials (piping, fasteners, plates, forgings) and welding materials (covered electrodes, submerged arc and wire gas protected combinations) and activities of laboratories for calibration, chemical, metallographic, mechanical testing and non destructive testing at Equipos Nucleares S.A., S.M.E (Ensa) Facilities in Avda. Juan Carlos I, 8, Apartado 51, 39600 Maliaño, Cantabria, Spain.

The information contained herein is confidential and no permission is granted to reproduce or disclose any part of this document.

In case of any interpretation conflict, English version shall govern.



**ISO NUCLEAR QUALITY ASSURANCE
 MANUAL**

SECTION	TITLE
General 1	Cover Sheet and Table of Contents
General 2	Statement of Authority and Company Policy
General 3	[Reserved]
General 4	[Reserved]
General 5	Definitions
General 6	[Reserved]
Section 01	Introduction
Section 02	Indoctrination and training
Section 03	Organization
Section 04	Context of the Organization and Leadership
Section 05	Design Control
Section 06	Specifications, procedures and drawings
Section 07	Document Control
Section 08	Control of purchased materials, items and services
Section 09	Process Control
Section 10	Welding
Section 11	Heat Treatment Control
Section 12	Non Destructive Examination
Section 13	Handling, storage, shipping and preservation
Section 14	Control of measuring and test equipment
Section 15	Non Conforming items
Section 16	Corrective Action
Section 17	Audits
Section 18	Quality Assurance Records
Section 19	Field Operations
Section 20	Process Map
Section 21	Implementación de UNE 73401
ENSA Prepared	ENSA Review and Approved
Quality Assurance Manager	Senior VP & Managing Director



STATEMENT OF AUTHORITY AND COMPANY POLICY

SECTION

General 2

The **Quality Policy of ENSA** is to develop Design, Engineering and Manufacturing activities of Products and Services considering **Nuclear Safety Culture** as an overriding priority and to satisfy Customer's and Legal requirements by the implementation of this Quality Program; with the **vision** to be a worldwide leader provider of multi-system equipment and services for nuclear power plants due to our operational excellence and service reliability.

This policy is aligned with Ensa's corporative **values**: Health and Safety, Customer Focus, Operative Excellence, Ethic, Innovation, Communication, Team building and Sense of Belonging.

The implementation of this policy will be achieved through the controlled system for the design, the construction of items, the supply of material and the provision of services established in this Quality Program to comply with applicable Legal and Code requirements and **Customer's expectations**.

Compliance with quality requirements is an interdisciplinary function that enforces **all personnel working for ENSA**, who inevitably must be involved in the **Nuclear Safety Culture, Risk Management** approach and the compliance of this **Quality Program** for the achievement of the objectives of quality and the **Continuous Improvement** established in the Company.

ENSA advocates a proactive approach to detect and prevent the intrusion of counterfeit, fraudulent, and suspect items (**CFSI**) into Safety Related equipment, components, systems, and structures.

Overall responsibility for implementing the Quality Program is formally conferred to the Quality Assurance Manager.

In case of differences between this Quality Manual and other ENSA documents, the Quality Manual will prevail, having to be reviewed the other documents.

Jose David Gomila Benitez
President & CEO



-RESERVED-

SECTION

General 3



**EQUIPOS NUC LEARES, S.A.
QUALITY ASSURANCE MANUAL**

PAGE 2 OF 1

QM-ISO Rev.15

-RESERVED-

SECTION **General 4**



DEFINITIONS

SECTION **General 5**

1.0 DEFINITIONS AND TERMS USED

2.0 ACRONYMS

DEFINITIONS

SECTION

General 5**1.0 DEFINITIONS AND TERMS USED****A**As Built Drawings

Drawings showing the item as actually constructed, with actual dimensions.

Activity

task which contributes to the realization of the products or services

CContract Number

Number assigned for each contract and reflected on the Work Order.

Customer

The organization buying from Ensa.

Commercial grade item or activity

item or activity that affects nuclear safety and that was not designed, manufactured or performed in accordance with specific nuclear requirements

Note 1 to entry: Commercial-grade items do not include items where the design and manufacturing process require in-process inspection and verification to ensure that defects or failures to comply are identified and corrected (i.e. where one or more critical characteristics of the item cannot be verified). Critical characteristics are important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Note 2 to entry: The determination of the critical characteristics, the means for verification and acceptance for intended safety functions are the responsibility of the customer.

Counterfeit items

Items that are intentionally manufactured, refurbished or altered to imitate original products without authorization in order to pass themselves off as genuine

DDesign Documents



DEFINITIONS

SECTION

General 5

All those reports, calculations, drawings and sketches used to show that the applicable design requirements of the Code and Owner Certified Design Specification, have been met.

E

Fraudulent items

Items that are intentionally misrepresented with intent to deceive

Note 1 to entry: Fraudulent items include items provided with incorrect identification, falsified or inaccurate certification. They may also include items sold by entities that have acquired the legal right to manufacture a specified quantity of an item but produce a larger quantity than authorized and sell the excess as legitimate inventory.

G

General Layout Drawings

Includes drawings such as General Assembly, General Outline and identification drawings. These drawings show the overall dimensions of the items to be constructed, identifying materials, welds and cladding.

Grade approach

Process or method employed to ensure that the application of the requirements related to quality management, documentation, monitoring and measurement is commensurate, with nuclear safety significance.

H

Hold Point

A designated stopping place during or following a specific activity at which inspection or examination from a designated organization is required before further work can be performed. Work shall not proceed beyond mandatory hold points without the written consent of the inspecting organization.

I

Indoctrination

Familiarization activity directed to Ensa personnel, with the purpose of getting them acquainted with the QA Manual and General Procedures requirements. This will help personnel whose activities are quality or safety related, in acquiring and understanding of the need and justification of Ensa's QA Program that will permit a better performance



DEFINITIONS

SECTION

General 5

of the QA related functions. It may be implemented through courses, talks, discussions, etc., held at Ensa.

Inspection

Examination or measurement to verify whether an item or activity conforms to specified requirements.

Inspection Point Plan (IPP)

A sequential listing of all inspection activities including document number and revision to which the activity conforms. It provides spaces for signature of Ensa, Authorized Nuclear Inspector; third party Inspection, Notified Body and Customer.

Integrated Project Schedule (IPS)

Document containing the list of documents, procurement and manufacturing activities and interface with customer for a specific contract. This document includes schedule information for such activities.

Item Number

The number included on drawings used to identify an item supplemented by a Serial number for a number of identical pieces.

Item

All-inclusive term used in place of any of the following: assembly, component, equipment, material, module, part, software, structure, sub-assembly, sub-system, system or unit

Important to nuclear safety ITNS

Characteristic of a product, service, item or activity, whose failure could result in undue radiation exposure of people or the environment

L

Licensee

Holder of a current authorization granted by the nuclear regulator to an organization that has the responsibility for the siting, design, construction, commissioning, operation or decommissioning of a nuclear installation

M

Manufacturing Drawings

Drawings used for fabrication, inspection and testing.



DEFINITIONS

SECTION

General 5

Material Inspection Plan (MIP)

The list of all examination, test and inspections to be performed on materials before releasing them for production. Each operation listed therein is referenced to applicable documents including revisions, certification and inspection status. May be prepared by Ensa or Ensa's vendors.

Material Procurement Drawings

Drawings which are prepared for the procurement of materials, including as necessary, dimensions and references for removal of test specimens.

N

Non Conformance Report (NCR)

A deficiency in characteristics, documentation or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Nuclear safety

Achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks

P

Procurement Documents

Contractually binding documents that identify and define the requirements which items or services must meet in order to be considered acceptable by Ensa.

R

Receiving Inspection

Inspection of purchased items and services at Ensa's Shop and Field Sites.

Review/Approval

As used in this Manual is denoted by signature/initials or stamps and date unless otherwise permitted by the electronic system by means of user and password.

Route Sheet (HR)

A sequential listing of all inspection and Manufacturing activities including document number and revision to which the activity conforms. It provides spaces for signature of Ensa, Authorized Nuclear Inspector; Third party Inspection, Notified Body and



DEFINITIONS

SECTION

General 5

Customer.

S

suspect items

Items where there is an indication or suspicion that it may not be genuine

T

Training

Activity focused to give the personnel who receive it, a sufficient level of knowledge or skill to adequately perform a function or to maintain or improve such a knowledge or skill that permits a successful performance.

V

Vendor

Organization that provides source materials, items or services. The term includes Certified or qualified Material Organizations, qualified Suppliers and Certificate Holders.

W

Witness Point

A manufacturing or inspection point requiring advanced notification, prior to the commencement of the operation, to the designee of the witness point. Operation may commence as scheduled with or without the presence of the designee of the witness point if such operation was properly notified to the parties involved.

2.0 ACRONYMS

C	Inspection point that request issuing of certificate.
CAR	Corrective Action Report
CAQ	Condition Adverse to Quality
CEO	Chief Executive Officer
CFSI	Counterfeit, Fraudulent, and Suspect Items.
CMTR	Certified Material Test Report
COC	Certificate of Compliance
CODI	Dimensional Control
CTA	Advanced Technology Center
DDS	Welding Development



DEFINITIONS

SECTION **General 5**

EOMR/RFF	End of Manufacturing Report
NDE/END	Non Destructive Essay
ENSA	Equipos Nucleares, Sociedad Anónima, Sociedad Mercantil Española.
H	Hold Point
HR	Route Sheet
IC	Complemetary Instruction
ILAC	International Laboratory Accreditation Cooperation
IP	Project Engineer
IPP/PPI/DSI	Inspection Point Plan (traveler)
IPS/ES	Integrated Project Schedule / Engineer Schedule
IR/ SR	Inspection Report
IT	Information Technology
ITNS	Important To Nuclear Safety
JP	Project Manager
GP	General Procedure
LT	Leak Test
MIP	Material Inspection Plan
MO	Material Organization
MR	Receiving Material Notice
MRA	Mutual Recognition Arrangement
MT	Magnetic Particle Test
NCR	Non Conformity Report
ODD	Document Distribution Office
ONA/ON/NB	Authorize Notify Body or Notify Body
OT	Work Order



DEFINITIONS

SECTION

General 5

PLM	Product Lifecycle Management (software)
PR	Purchase Request
PO	Purchase Order
PQR	Welding Procedure Qualification Record
PQP	Project Quality Plan
PT	Liquid penetrat Test
PWHT	Post Weld Heat Treatment
RT	Radiographic Essay
SE	Testing request
SEPI	Sociedad Estatal de Participaciones Industriales
SP	Specific Procedure
SQAR	Supplementary Quality Assurance Requirement
SQR	Specification Qualification Record
SIDOCO	Documentary System Control (software)
QA	Quality Assurance
QAE	Quality Assurance Engineer
QAM	Quality Assurance Manager
QAS	Supply Control Engineer
QC	Quality Control
QM	Quality Manual
QP	Quality Plan
QVL	Quality Vendor List
TP/TPI	Third Party / Independent Third Party
UM	Utilization of Material non designated
UT	Ultrasonic Test
VN	Voucher Request
VP	Vice-President
VQR	Vendor Quality Requirement
VT	Visual Essay
W	Witness Point
WR	Welding Record
WQR	Welder Qualification Record
WPS	Welding Procedure Specification



**EQUIPOS NUC LEARES, S.A.
QUALITY ASSURANCE MANUAL**

PAGE 2 OF 1

QM-ISO Rev.15

-RESERVED -

SECTION **General 6**



INTRODUCTION

SECTION **01**

- 1.0 PURPOSE
- 1.1 SCOPE
- 1.2 RESPONSIBILITIES
- 1.3 ADMINISTRATION AND CONTROL OF THE QUALITY MANUAL
- 1.4 DISTRIBUTION AND CONTROL OF THE QUALITY MANUAL



INTRODUCTION

SECTION 01

1.0. PURPOSE

The purpose of this Quality Assurance Manual (QAM), hereafter referred to as the Manual, is to provide a systematic method to establish and execute a Quality Assurance Program to control the quality of parts, equipment and services supplied by EQUIPOS NUCLEARES, S.A., S.M.E. (Ensa). Those considered products and services important to nuclear safety (INTS) must ensure nuclear safety during operation.

The “grade approach” methodology has been implemented in different sections of the manual and procedures based on the nuclear safety significance of the service or product.

This manual is based on:

- ISO 9001:2015. Quality management systems - Requirements.
- ISO 19.443:2018. Quality management systems - Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS).
- KTA-1401 (2017-11). General Requirements for the Quality Assurance.
- UNE-ISO 73.401:1995. Nuclear Facilities. Quality Assurance.
- Safety Instruction IS-12. Requirements for qualification and training of personnel in the scope of nuclear installations.
- Safety Instruction IS-19. Management system requirements for nuclear installations.
- Safety Instruction IS-20. Safety requirements for storage cask of spent fuel.
- Safety Instruction IS-24. In-service inspection in nuclear installations
- Safety Guideline 06.01. Quality assurance for radioactive material transportation.
- Safety Guideline 10.1. Basic guide of quality assurance for nuclear installations
- Safety Guideline 10.2. Documentation system under quality assurance programs of nuclear installations.
- Safety Guideline 10.3. Quality assurance audits.
- Safety Guideline 10.6. Design Quality assurance for nuclear installations.
- Safety Guideline 10.9. Quality assurance of safety related software for nuclear installations.
- Safety Guideline 10.10. Qualification and certification of personnel who perform nondestructive test.
- Safety Guideline 10.13. Quality assurance for dismantling and closure of nuclear installations.
- 10CFR50 Ap.B. Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants- NRC
- 10CFR71 Subpart H. Quality Assurance - NRC
- 10CFR72 Subpart G. Quality Assurance - NRC
- GSR Part 2 Leadership and Management for Safety - IEAE

1.1. SCOPE

The scope covers all activities affecting quality from bid and contract evaluation, technical design, purchasing, manufacturing, inspecting, examination, testing, vendors



INTRODUCTION

SECTION 01

evaluation and control, detection of nonconforming items, corrective actions, analysis of its sources, certification and records, to delivery of the item including supply of material. Item installation at field sites is also covered by [Section 19](#) of this Manual.

The Quality Assurance Program is implemented in accordance with the Specifications, Procedures and policies embodied and/or identified in this Manual.

Specific additional Customer requirements that may supplement the requirements set in this Quality Manual will be collected in specific Project Quality Plans (PQP) [Exhibit 06.11](#) for each contract as considered necessary by the Quality Assurance Manager (QAM).

1.2. RESPONSIBILITIES

The overall responsibility for the items constructed by Ensa belongs to the "President & CEO". Total responsibility for the planning and implementation of the Quality Program is vested in the "Quality Assurance Manager" who has the authority and responsibility for assuring full compliance with the quality requirements, defined in this Manual, and with the Code and Customer's requirements. VPs and other people in charge of the different areas are responsible for supporting and implementing this Manual in their respective areas.

The "Quality Assurance Manager" is independent on manufacturing, delivery terms or budgets to assure full compliance with the Quality Program. Consequently, he/she has direct access to the "Senior VP Managing Director".

At least every two (2) months, the QAM shall report in writing to the "President & CEO", "Senior VP & Managing Director", Directors and others as deemed necessary, for evaluating quality trends or quality problems. If instructions are to be transmitted, the "Senior VP & Managing Director" will formally document them on a copy returned to Quality Assurance.

Once a year, the Management performs a review of the Quality Management System. The information used by the Managing Staff to assess the adequacy and effective implementation of the program and the need for the revision of the Quality System includes at minimum:

- Status of the actions from previous management review
- Changes in external and internal issues that are relevant to the Quality System
- Information on the performance and effectiveness of the quality management system, including trends and indicators for:
 - Customer satisfaction and feedback from relevant interested parties.
 - The extend of which quality objectives have been met.
 - Performance of processes and conformity of products and services.
 - Nonconformities and corrective actions.
 - Monitoring and measurement results.
 - Audit results.
 - Performance of external suppliers.
- adequacy of resources.



INTRODUCTION

SECTION 01

- effectiveness of taken actions to address risks and opportunities.
- opportunities and lessons learned from nuclear experience for improvement.
- Adequacy of quality management procedures.

The QAM is independent from any production or budgetary pressure and has enough authority and organization freedom to:

1. Identify quality problems.
2. Initiate, recommend or provide solutions to quality problems through the system established on this manual.
3. Verify implementation of solutions assuring control until proper disposition of non-conformance has occurred.
4. The QAM has the authority to stop work on any items subject to control by this Manual when, in his opinion, this action is deemed necessary to assure compliance with the quality requirements.

[Section 15](#) and [Section 08](#) of this Manual establishes the authority for "Quality Assurance" personnel detecting or being informed of a non-conformity to identify the element and take the action there indicated in respect to the stopping of work.

1.3. ADMINISTRATION AND CONTROL OF THE QUALITY MANUAL

The QAM prepares the Quality Manual (QM) and submit it to "Senior VP & Managing Director" for reviewed and approval. QAM issues it via SIDOCO system and is responsible for its maintenance. External copies are available through authorized accesses controlled by "Information Technology Systems Manager".

1.3.1. -Reserved-

1.3.2. The latest revised paragraph or sentence is identified by a vertical line on the left-hand margin.

1.3.3. The QAM submit the changes to "Senior VP & Managing Director" for reviewed and approval.

1.3.4. -Reserved-.

1.3.5 The references made to general and specific procedures and exhibits in the sections of the manual may be consulted within the SIDOCO application.

1.3.6 Revised exhibits shall be distributed into SIDOCO or PLM system. Minor changes that do not affect to the main content, do not implicate a new QM revision.

1.4. DISTRIBUTION AND CONTROL OF THE QUALITY ASSURANCE MANUAL

1.4.1. Following acceptance, the access to the QM is made via Internet through a name and a password. The control of names and passwords is established by "Information Technology Systems Manager". Names cannot be changed but



INTRODUCTION

SECTION **01**

passwords or access keys may be so for security purposes. All paper copies or any other electronic copy of this QM are considered non-controlled copies and are only valid on the date they are provided to users. This is indicated at the footage of the printouts. The non-controlled copies will not be updated and will be valid on the issuing date.

The Distribution List of the Manual with authorization for access to external users is controlled by "Information Technology Systems Manager".

- 1.4.2** Within Ensa all personnel have access to the latest approved QM through the SIDOCO application. Following acceptance of changes to the QM, the revised edition is posted on the Ensa SIDOCO application with the distribution date. The QM revision and accepted changes will be notified to all Ensa's personnel via e-mail. In the case of Ensa personnel, any change considered significant by QAM will be communicated via additional indoctrination and training program to the affected units. As in the case of all indoctrination and training, records shall be maintained.

External personnel with access to the QM shall be notified by e-mail when a new revision is released.



INDOCTRINATION AND TRAINING

SECTION **02**

2.0 PURPOSE

2.1 QUALITY INDOCTRINATION

2.2 TRAINING AND QUALIFICATION

2.3 QUALIFICATION OF QUALITY PROGRAM AUDIT PERSONNEL

REFERENCES



INDOCTRINATION AND TRAINING

2.0. PURPOSE

To provide measures for indoctrination and training of personnel performing or managing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

2.1 QUALITY INDOCTRINATION

QAM is responsible for identifying personnel performing and managing activities affecting Quality. This is in part, in the form of matrix (See [Exhibit 02.18](#)) which against the description of the unit the staff belongs to, identifies the sections of this manual or General Procedures (GP) to be indoctrinated.

In any event, all new employees receive a basic indoctrination into the company's Quality Policy and QA Program. Further, once they are allocated to a position in an area/unit they receive indoctrination in the sections and procedures identified in the matrix.

"Area Managers" may also perform indoctrination in specific quality requirements such as procedure details, relevant to that area activity. Indoctrination may be conducted through formal presentations, discussions groups, on the job training, e-mails or self-reading but in any event the training sessions must be registered or confirmed in the certification.

2.2 TRAINING AND QUALIFICATION

All personnel with functions assigned or described within this QM shall be properly trained to assure that their work performance meets appropriate standards. Special emphasis is placed on the following areas to qualified the personnel: Welding [Exhibit 02.04](#), Non-Destructive Examination, Heat Treatment, Lifting, Testing & Inspection, Certifying Engineer [Exhibit 02.05](#) and Lead Auditor [Exhibit 02.13](#). New or transferred employees shall be trained, and qualified if required, in their job assignment prior to performing duties affecting quality.

Procedures [GP.02.01](#), [GP.02.09](#), [GP.05.19](#) and [GP.12.01](#) contain the requirements for personnel training , qualification and performance evaluation. The procedures shall:

- Address personnel selection, indoctrination, training, determination of initial capability and evaluation of performance.
- Identify any special physical characteristics needed in the performance of each activity (ex: visual acuity [Exhibit 02.01](#), [Exhibit 02.02](#)).
- Define the evaluation of the performance at periodic intervals, not to exceed three (3) years by the responsible Manager, except NDE Level III personnel which shall be evaluated not to exceed five (5) years.
- Any person who has not performed inspection or testing activities in his qualified area for a period of one (1) year shall be reevaluated by re-determination of required capability in accordance with the procedure.
- Identification of the exhibit to record the training and qualification (ex. [Exhibit 02.15](#), [Exhibit 02.14](#), [Exhibit 02.05](#), [Exhibit 02.16](#), [Exhibit 02.19](#), [Exhibit 02.20](#))

Continuous indoctrination and training courses are planned and implemented by the



INDOCTRINATION AND TRAINING

SECTION **02**

person in charge of the different areas and/or his delegate upon the need for qualified personnel. Scheduled courses shall be included a "Indoctrination and Training Plan" managed by "Human Talent Manager".

Additional indoctrination or training may be necessary in the event of significant changes to this Manual, changes in GP or in specific quality requirements for a given customer or due to relevant incidents or other situations.

All indoctrination and training records [Exhibit 02.07](#) shall contain as minimum, the following information:

- Name(s) of trainee(s).
- Subject of indoctrination and training.
- Date and duration of session.
- Name of trainer.
- Trained personnel.

Indoctrination and training records are sent to "Human Talent" unit for filing, however the QAM has access to the necessary records.

The qualification of personnel shall be certified in an Ensa's form, including the following information:

- Ensa's logo.
- Identification of person being certified.
- Activities certified to perform.
- Basis used for certification, which includes such factors as:
 - o Education, experience, indoctrination and training.
 - o Test results, where applicable.
 - o Results of capability demonstration or written examination.
 - o Results of periodic evaluation.
 - o Results of physical examination when required by procedure.
- Signature of the person(s) designated in the General Procedure as responsible for the certification.
- Date of certification and date of recertification.

Qualification records are responsibility of the direct responsible of the personnel: "Area Managers" or "Unit Managers". They are stored in SIDOCO.

2.3. QUALIFICATION OF QUALITY PROGRAM AUDIT PERSONNEL



INDOCTRINATION AND TRAINING

SECTION **02**

Lead Auditors are qualified in accordance with [GP.02.01](#). The procedure shall address communication skills, training, audit participation, written examination and maintenance of qualification.

Personnel selected for quality assurance auditing assignments shall have experience and training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by training in one or more of the following Methods:

- Orientation to provide knowledge and understanding of nuclear related codes.
- External or internal training program in audit performance.
- On the job audit training as an Auditor-in-training or Technical Specialist under the direction of a qualified Lead Auditor.

The prospective Lead Auditor shall have participated in a minimum of five (5) quality audits within a period of time not to exceed three (3) years prior to the date of qualification, one audit of which shall be a nuclear quality audit within the year prior to his qualification. Based on annual assessment by the QAM, the qualification may be extended, require retraining or require re-qualification. These assessments shall be documented.

Lead Auditors who fail to maintain their proficiency for a period of two (2) years shall require re-qualification by retraining, reexamination and participation in at least one nuclear audit prior to recertification.

REFERENCES

- [Exhibit 02.01](#) Visual Examination
- [Exhibit 02.02](#) Visual Examination for Crane Operators
- [Exhibit 02.04](#) Welding Operator Qualification Test Record
- [Exhibit 02.05](#) Design and Analysis Engineer Certificate
- [Exhibit 02.06](#) Training and experience data sheet
- [Exhibit 02.07](#) Attendance course sheet
- [Exhibit 02.13](#) Lead auditor Qualification
- [Exhibit 02.14](#) Personnel Qualification Record for Welding Technician
- [Exhibit 02.15](#) General Personnel Qualification Record for GP 2.9
- [Exhibit 02.16](#) Personnel Qualification Record for Machining Operators
- [Exhibit 02.18](#) Matrix for General Indoctrination on Ensa Quality System
- [Exhibit 02.19](#) Personnel Recertification Certificate (Dimensional Control)
- [Exhibit 02.20](#) General On Site Personnel Qualification Record for GP 2.9



ORGANIZATION

SECTION **03**

SECTION 03- TABLE OF CONTENTS

- 3.0 PURPOSE
- 3.1 PRESIDENT & CEO
- 3.2 SENIOR VP & MANAGING DIRECTOR
- 3.3 VP FINANCE, SYSTEMS AND QUALITY
- 3.4 VP OPERATIONS AND APPLIED INNOVATIVE TECHNOLOGY
- 3.5 VP LEGAL COUNSEL AND HUMAN RESOURCES
- 3.6 VP BUSINESS DEVELOPMENT AND SUBSIDIARIES
- 3.7 VP AUDITING AND CONTROL
- 3.8 DELEGATION OF AUTHORITY
- 3. 9. ORGANIZATION CHARTS



ORGANIZATION

SECTION 03

3.0. PURPOSE

This section describes Ensa's organization, and responsibilities and their interfaces and dependencies. (See Organization Charts at the end of this section).

3.1 PRESIDENT & CEO

He is responsible for all the activities performed in Ensa and for the compliance with all the requirements stated in this QM and coordination of the areas reporting directly to him. His responsibilities include:

- Establishing Policies and Objectives,
- Lead and convene the Board Meetings,
- VP Legal Consulting and Human Resources,
- Corporate communication.

3.2 SENIOR VP & MANAGING DIRECTOR

Reports directly to the "President & CEO" and is responsible for the surveillance and coordination of the areas reporting directly to him:

- VP Finance, Systems and Quality,
- VP Operations and Applied Innovative Technology ,
- VP Business Development and Subsidiaries,
- Responsible of "Marketing and Sales of Nuclear Business".

The main responsibilities include the establishment of the commercial policy within his area and the relationship with the Customers. Also he will be in charge of implementing the marketing and sales program, preparation of proposals and sales and contractual negotiation with the Customers as well as the Order's acceptance.

These duties are described in [GP.03.05](#) and performed through:

- Marketing and Sales,
- Estimating and Proposals.

3.3. VP FINANCE, SYSTEMS AND QUALITY

Reports directly to the "Senior VP Managing Director" and the main responsibilities include all activities concerning "Quality Assurance, Environment and Organization", "Administration and Finance", "Digital Transformation and Information Technology System" and "Procurement". These responsibilities are accomplished through:

- Quality Assurance, Culture, Reliability and Improvement and Organization: described in [GP.03.01](#)
- Procurement: described in [GP.03.02.04](#).
- Administration and Finance: described in [GP.03.04](#).
- Information Technology System: described in [GP.03.04](#).

QC personnel shall refer thereafter into this QM to NDE operators and Quality Control.

3.4 VP OPERATIONS AND APPLIED INNOVATIVE TECHNOLOGY

Reports directly to the "Senior VP & Managing Director" and his main responsibilities are defined in [GP.03.02](#). These are to assure the establishment, implementation and



ORGANIZATION

SECTION **03**

compliance with this QM for the manufacturing of the orders awarded to Ensa. These functions are accomplished by:

- Production: described in [GP.03.02.01](#),
- Projects and Engineering: described in [GP.03.08](#) and [GP.03.02.03](#),
- General Planning: described in [GP.03.08](#),
- Advanced Technology Center – R&D: described in [GP.03.02.02](#).

3.5 VP LEGAL COUNSEL AND HUMAN RESOURCES

Reports directly to the "President & CEO" and is responsible for establishing the political labor aligned with the company mission and goals and sustainability culture. These duties are described in [GP.03.09](#) and performed through:

- Special Projects and Services,
- Technical Development

3.6 VP BUSINESS DEVELOPMENT AND SUBSIDIARIES

Reports directly to the "Senior VP Managing Director" and the main responsibilities include the establishment of the commercial policy within his area and the relationship with the Customers. Also, he will be in charge of implementing the marketing and sales program, preparation of proposals and sales and contractual negotiation with the Customers as well as the order's acceptance and control of project management up to their delivery for field site activities and diversification activities. These duties are described in [GP.03.06](#) and performed through:

- Legal counsel,
- Compliance,
- Human talent management,
- Health and safety.

3.7. VP AUDITING AND CONTROL

With direct reporting to the President & CEO. These duties are described in [GP.03.03](#) and performed through:

- To analyse and interpret the information for the Managing Staff,
- To supervise the reports for the Shareholders and External Agents,
- To define the goals and supervise their operative performance,
- To supervise the procedures for the Internal Managing Control to ensure the validity of the information,
- To perform the Operational Audits,
- To elaborate for the Managing Staff the Management Control Reports for decision-making,
- To control the performance and results of decisions agreed by the Managing Staff.

3.8. DELEGATION OF AUTHORITY

Responsibilities assigned by this QM to an area or unit, shall be understood to be the Manager of that area or unit.

ORGANIZATION

SECTION 03

Each person in a supervisory position may delegate the performance of their duties to competent and when required qualified certified personnel under their supervision. However, they may not delegate their responsibility.

Each person in a supervisory position may carry out the duties of personnel under their supervision, provided they are qualified and certified to perform the work, when required.

3.9. ORGANIZATION CHARTS

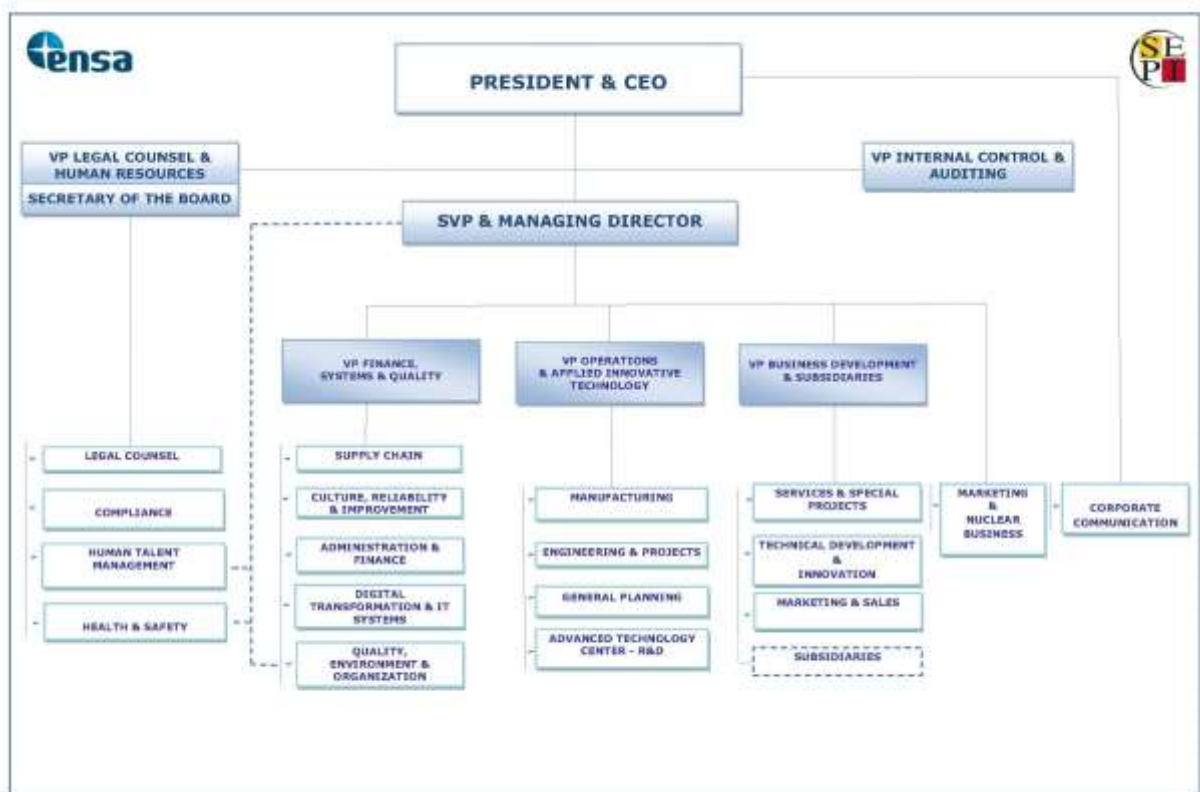


Fig.3.1 : General Organization

———— Organization line
 - - - - - See Section 01

ORGANIZATION

SECTION **03**

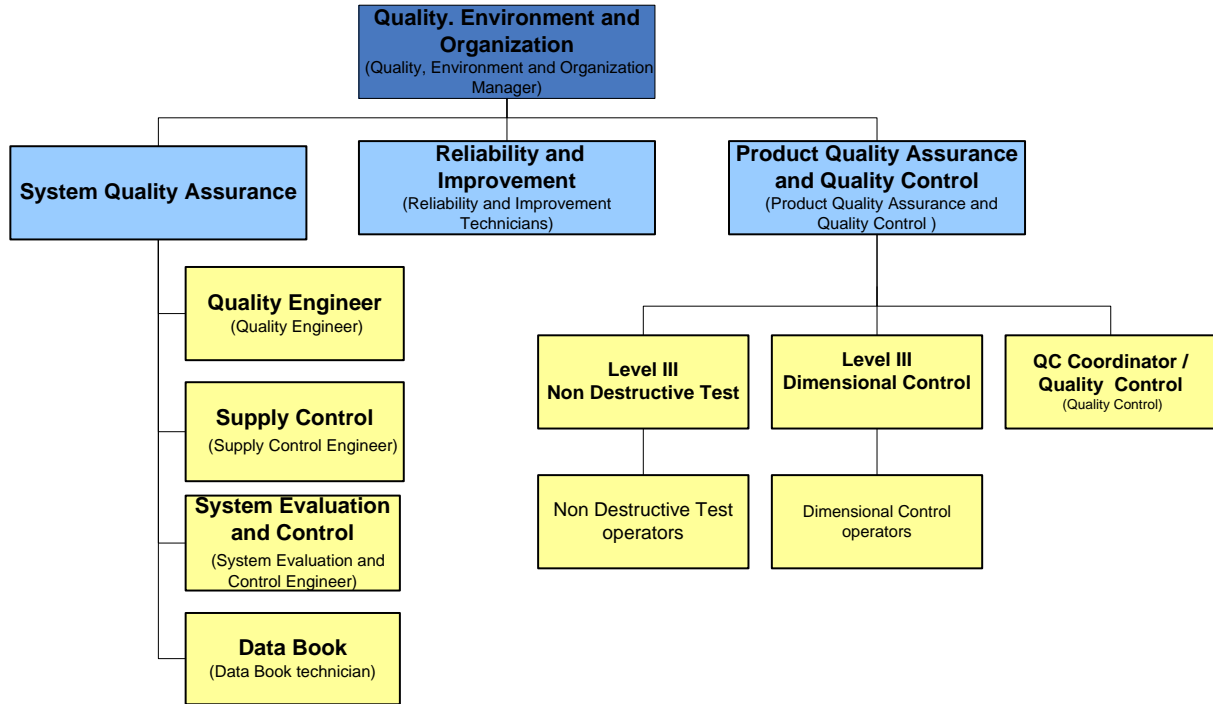


Fig.3.2 : Quality Assurance Area

Note: hereafter the following acronyms are used.

QAE: Quality Assurance Engineer

QAS: Supply Control Engineer

QC: Quality Controller or Quality Control Coordinator

NDT = NDE : Non Destructive Testing or Non Destructive Examinations are used with the same meaning.

ORGANIZATION

SECTION **03**

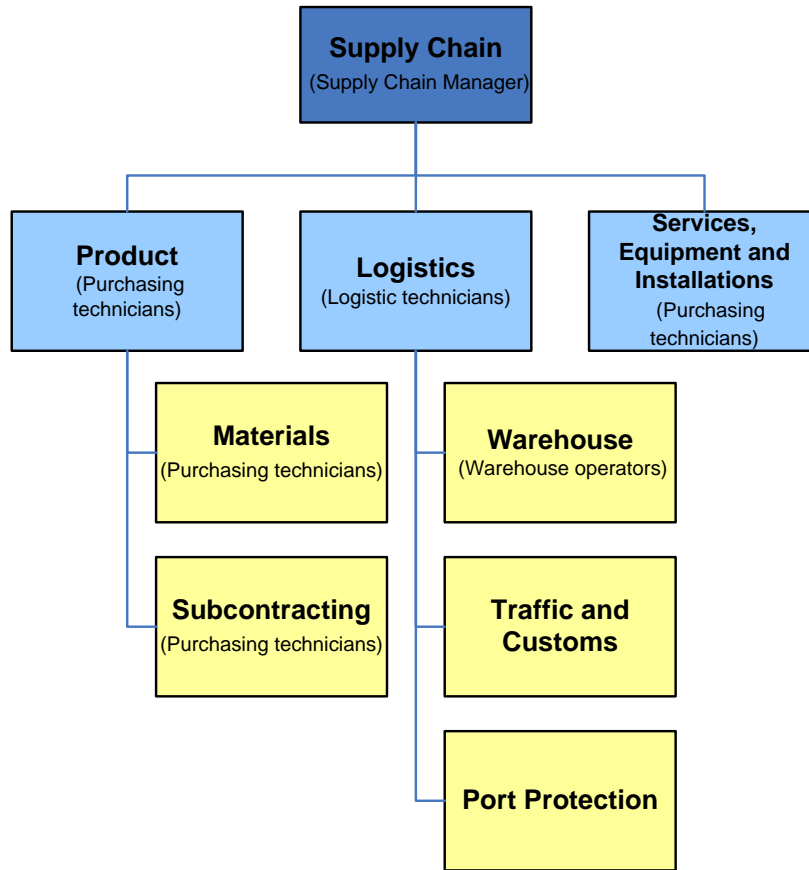


Fig.3.3 : Procurement Area

ORGANIZATION

SECTION **03**

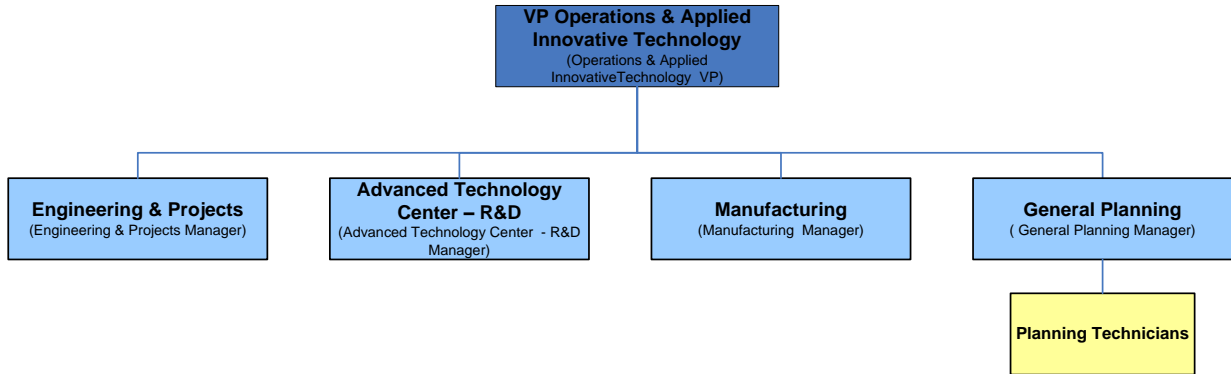


Fig.3.4 : VP Operations & Applied Innovative Technology

ORGANIZATION

SECTION **03**

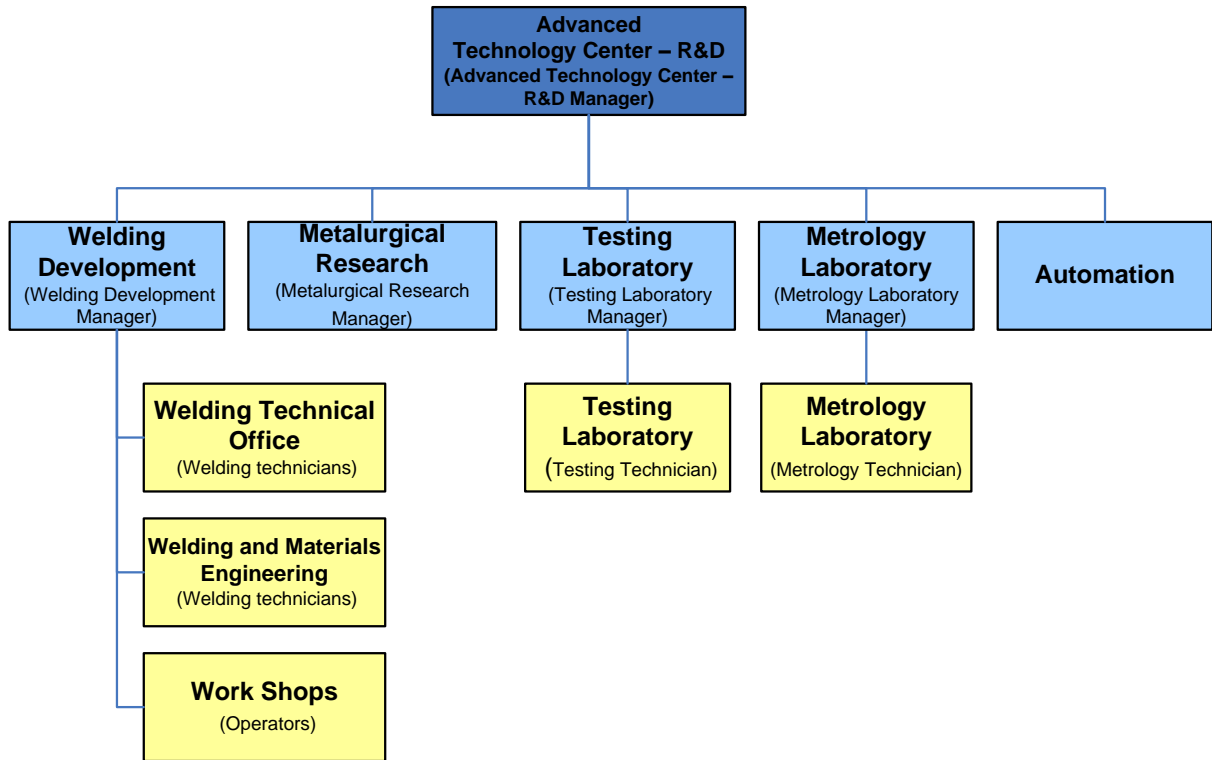


Fig.3.5 : Advance Technology Center – R&D Area

ORGANIZATION

SECTION **03**

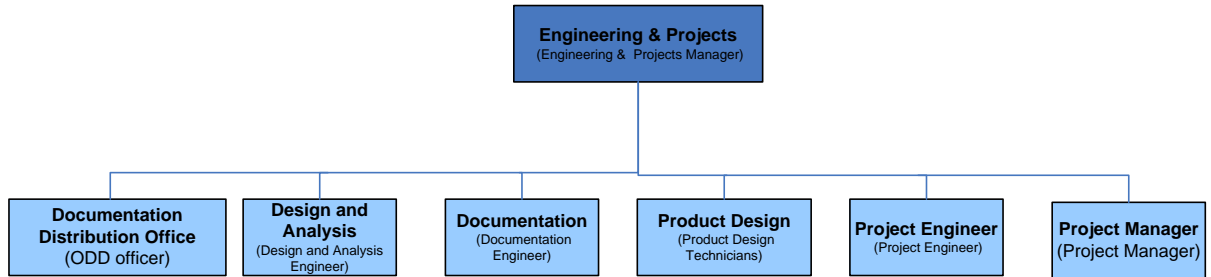


Fig.3.6 : Engineering and Projects Area

ORGANIZATION

SECTION **03**

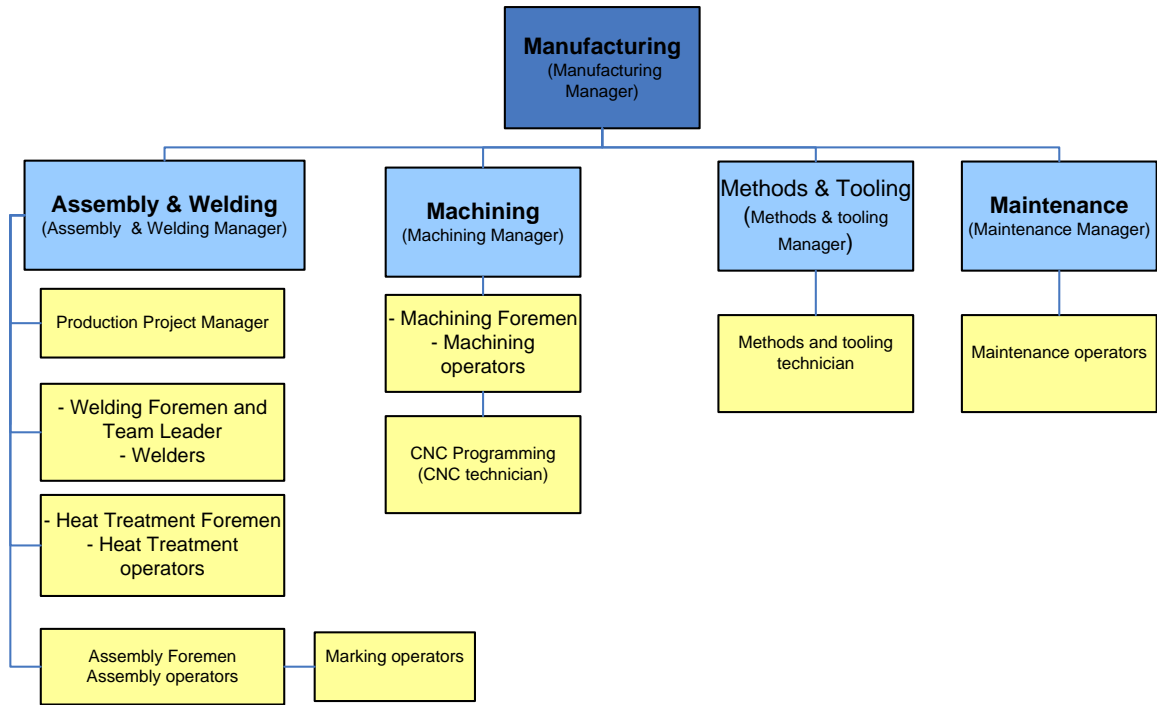


Fig.3.7 : Manufacturing Area

ORGANIZATION

SECTION **03**

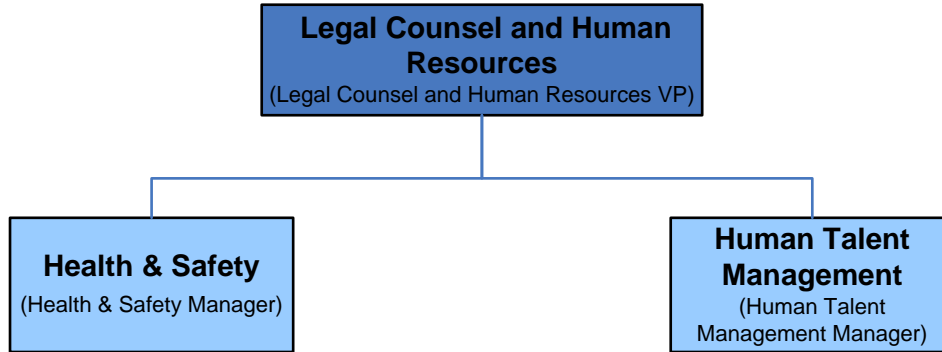


Fig.3.8 : VP Legal Counsel And Human Resources

ORGANIZATION

SECTION **03**

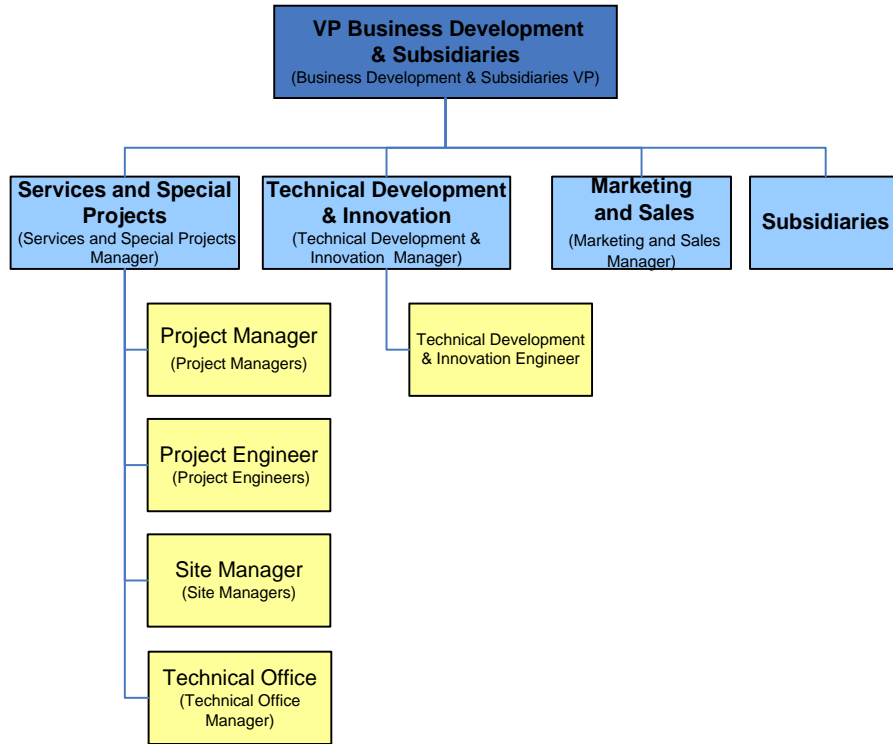


Fig.3.9 : VP Business Development And Subsidiaries



CONTEXT OF THE ORGANIZATION AND LEADERSHIP

SECTION **04**

- 4.0 PURPOSE
- 4.1 CONTEXT OF THE ORGANIZATION
- 4.2 LEADERSHIP
- 4.3 NUCLEAR SAFETY CULTURE (NSC)
- 4.4 PLANNING
- 4.5 PROCESSES
- REFERENCES



4.0.PURPOSE

To describe the context of the organization, interested parties and its expectations in order to be taken into account by the management to define the corporative culture, mission, vision, values and the strategic planification.

4.1 CONTEXT OF THE ORGANIZATION

Ensa, "Equipos Nucleares" S.A, S.M.E is 100% owned by the Spanish public holding SEPI ("Sociedad Estatal de Participaciones Industriales"). SEPI is a public-law entity whose activities are regulated by private law, and which is attached to the "Ministerio de Hacienda y Administraciones Públicas" (Ministry of Finance and Public Administrations) and reports directly to the Minister.

Ensa was founded on July 10th 1973 to satisfy the demands of the Spanish nuclear civil program pertaining to the manufacturing of large nuclear components. The construction of the plant, located in Maliaño (Cantabria), south of the Bay of Santander, and next to the city, took place during 1975 and 1976. The first manufacturing components for the Spanish market began on those years.

The main activity is the manufacturing and installation of mechanical components for Nuclear Power Plants. Ensa understands the expectations of the **nuclear business** related to:

- Engagement with Nuclear Safety Culture
- Operational excellence and continuous improvement through high technology developments.
- Flexibility to adapt for different designs and adaptation of the manufacturing process
- Utilization of Human Performance tools in the daily activities.
- Implementation of provisions for CFSI detection
- Information protection

The products are mainly heavy components, supply of stock base metal materials, test services and certification of metallic materials, installation and repair of mechanical equipment and piping, design and construction of spent fuel casks, etc... in compliance with customer requirements, regulations, codes and applicable standards.

Most of our items are under **nuclear legal regulation** and the surveillance of Notify Bodys (NB) appointed by the national regulator in accordance with the national regulation of the country where the product is installed, or the service is performed.

The scope of the applicability covers all activities affecting quality from bid and contract, technical design, purchasing, manufacturing, examination, testing, detection of nonconforming items, corrective and preventive actions, audits, records, training, installation and post-service, to analysis and improvement activities according to the contractually specified requirements of the Customer.

Requirements are transmitted to our **Suppliers and Sub-Contractors** depending on the scope defined in our purchase order based on the classification of the procurement in



CONTEXT OF THE ORGANIZATION AND LEADERSHIP

SECTION **04**

accordance with the grade approach and the type of activity.

Workers and unions are an essential part of the company and ENSA promotes the needed for a correct environment, circumstances and conditions to develop our activity efficiently at no risks and avoiding incidents and damages affecting the health and the integrity of our employees.

The respect of all rights of the persons and organizations we work with and, in general, with the **society** and contributing to the sustainable growth evaluating the social and environmental consequences of our performance is considered through ethic operation and social responsibility, communication and team building.

Every year is performed a Strengths, Weakness, Opportunities and Threads (SWOT) analysis to review risk and opportunities that could affect to the quality system. See [Exhibit 04.02](#). Improvement plans are issued to manage actions.

Needs and expectations of Interested parties are identified and controlled in [Exhibit 04.01](#). Its review is performed, at least, during "Management review meeting".

4.2. CUSTOMER APPROACH

The Managing Staff has to make sure that the requirements established by the Customers are known during a launching meeting of the projects. This meeting is conveyed once the contract is received from the Customer. Nuclear Business or Business Development is in charge of transmitting the contractual documents to all areas involved allowing a reasonable time for reading and acknowledge them before fixing the meeting.

During the meeting the main Customer requirements and details are transmitted and all doubts and questions are exposed for a potential change/comment, if any as described in section 5 of Quality Assurance Manual and/or GP 5.X.

The Customer Satisfaction Assessment is performed according to Section 11 of this Manual.

4.3. NUCLEAR SAFETY CULTURE (NSC)

The Managing Staff is committed with Nuclear Safety as indicated in the Policy and promotes it through all organization to ensure awareness by all personnel. Several methods are used such as:

- Issuance of procedure to describe different actions related with the implementation of NSC in Ensa. [GP.05.32](#)
- Communication
- Indoctrination (based on INPO traits).

4.4 PLANNING

4.4.1 Quality Goals

The Managing Staff establishes on a yearly basis such goals which have currently



CONTEXT OF THE ORGANIZATION AND LEADERSHIP

SECTION **04**

been translated into different Indicators liable to measure and which are reported in the periodic Quality reports.

These indicators/goals are part of the report that is issued at least bimonthly by Quality Assurance.

Aforementioned goals/indicators are established at the beginning of the year and are published via SIDOCO for knowledge and use of all ENSA personnel.

4.4.2 Planning of the Quality Management System

The Quality Management System established in this Manual has been programmed to achieve the compliance with the requirements and it is yearly review during the "Management Review Meeting" See [Exhibit 04.04](#).

4.5 PROCESSES

Process map is presented in [Section 20](#) of this manual. Process data sheets are recorded in [Exhibit 04.03](#).

REFERENCES

- [Exhibit 04.01](#) Needs and expectations of interested parties
- [Exhibit 04.02](#) DAFO Analysis
- [Exhibit 04.03](#) Process data sheet
- [Exhibit 04.04](#) Management review
- [Exhibit 04.05](#) Monthly quality report



DESIGN CONTROL

SECTION **05**

- 5.0 PURPOSE
- 5.1 REVIEW OF INQUIRIES
- 5.2 ORDER ENTRY
- 5.3 CONTRACTUAL CHANGES
- 5.4 DESIGN
- 5.5 DESIGN DRAWINGS
- 5.6 SPECIFICATIONS AND CONSTRUCTION PROCEDURES
- 5.7 CONTROLLED DOCUMENTS DISTRIBUTION
- 5.8 GRADE APPROACH
- REFERENCES



DESIGN CONTROL

SECTION **05**

5.0. PURPOSE

To define and implement systems which assure that the specified design requirements (ex.: Procurement Specifications, Owner's Certified Design Specifications, regulatory requirements, codes and standards) are correctly translated into specifications, drawings, procedures and instructions, utilized for the production or service.

5.1. REVIEW OF INQUIRIES

Design control activities begin upon receipt of Customer's request for quotation. All customer's request for quotation are received or directed to "Marketing and Sales" unit .

In accordance with [GP.05.10](#), "Marketing and Sales" is responsible for obtaining documented review and comments from other units or areas as applicable. It shall encompass the adequacy of quality requirements, verification that scope of work is within the scope of Ensa certifications and accreditations held and compliance with customer and regulatory requirements. "Marketing and Sales" personnel are also responsible of the preparation and negotiation of the offer.

A Risk Analysis may be performed in accordance with [GP.05.33](#) and documented with the exhibit [Exhibit 05.08](#).

5.2. ORDER ENTRY

Customer letter of intent and/or purchase order is received by "VP Nuclear Business" or "VP Business Development" for review against the offer and confirmation purposes. Conflicts between the contract and the offer or Code requirements are brought to the attention of the Customer by "VP Nuclear Business" or "VP Business Development".

Once an order has been accepted, "VP Nuclear Business" or "VP Business Development" responsible applies for a "Contract number" to "VP Finance, System and Quality". He informs Ensa's areas of the scope of the work to be carried out. "Engineering and Projects Manager" appoints a "Project Manager" (JP) who is responsible for maintaining the interfaces with the Customer and the issuance the "Work Order" (OT) ([Exhibit 05.01](#).) to provide summarized information of the project and a "Project Engineer" (IP). It is archived in PLM with all applicable contractual documents.

JP is the responsible of the customer communication to provide information relating with products, services, handling enquires, handling or controlling customer property, establishing specific requirements for contingency actions, when necessary.

"Planning Technician" issues the basis for planning preparation (ex: design activities, drawings, procedures, specifications ..), procurements, manufacturing, control and test activities. It is recorded in an Integrated Project Schedule (IPS) (see [Exhibit 07.10](#)).

"Planning Technician" and JP, based on the IPS, check the availability of internal resources such as buildings, equipment, information system, tooling, workshop capacity, etc. In case external resources are necessary, it will be managed through request to Procurement department in accordance with [Section 8](#). Human resources are analyzed periodically by "Human Resources Manager" in collaboration with "Planning Manager" and rest of Area Managers. The target of these verifications is to ensure the utilization



of the required resource in the correct moment to ensure quality and nuclear safety. If during the project it is detected any additional resource, it will be managed in the same way.

5.3. CONTRACTUAL CHANGES

JP processes all subsequent contractual changes in the same manner as the original contract. The accepted contractual changes are routed internally as for the original order as defined in [GP.05.16](#) and documented through [Exhibit 05.09](#).

5.4. DESIGN

5.4.1. Design input

"Engineering & Project Manager" appoints a "Design and Analysis Engineer" for the project. "Design and Analysis Engineer" organizes a "Design Input Meeting" in timely bases to define the "Design Inputs" to permit design activities to be carried out and to provide a consistent basis for making design conditions, accomplishing design verification and evaluation design changes. Design inputs are documented in the "Design Input Review" ([Exhibit 05.15](#)) and translated into design documents.

"Design Input Review" includes, as minimum:

- Definition of the scope of work.
- Definition of design inputs, and their sources (codes and standards, regulatory requirements, results of literature searches or other applicable background data, lessons learned
- Applicable codes and standards
- Definition of all computer design analysis activities (computer type, computer program, revision identification computer program verification, limitations...).
- Design method and identification of assumptions and indication of those that must be verified as the design proceeds.

"Design and Analysis Engineer" shall establish with the customer the system of units applicable for the nameplate and fabrication drawings. Alternate units (SI; US customary or local customary units) can be shown parenthetically. Whenever local customary units are used, source of the conversion factors shall be subject to verification and acceptance of the customer.

"Design and Analysis Engineer" will identify design interfaces when performed by different parties.

In case it is identified certain stages requiring authorization before progressing to the next stage, it will be included in the "Design Input Review".

5.4.2. Design Process

Design process is performed by "Design and Analysis Engineer" in a planned, controlled in accordance with [GP.05.01](#).

DESIGN CONTROLSECTION **05**

The output of the design process are design & analysis documents. Design analysis document shall:

- be sufficient detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse the originator.
- be legible and be in a form suitable for reproduction, filing and retrieval.

Design & analysis document must include, as minimum:

- Definition of the scope of work and objective of the analysis.
- Definition of design inputs, and their sources
- results of literature searches or other applicable background data, lessons learned.
- assumptions and indication of those that must be verified as the design proceeds.
- Identification of any computer calculation, including computer type, computer program (e.g. name) revision identification, inputs, outputs, evidence of or a reference to computer program verification, and the bases (or reference thereto) supporting application of the computer program to the specific physical problem.
- Review and approval.

Design and analysis documents such as:

- Basic Sizing Calculation [Exhibit 05.07](#).
- Design Reports , such as Work Request [Exhibit 05.07](#) or [Exhibit 05.14](#)
- Drawings [Exhibit \(05.03](#), [Exhibit 05.24](#), [Exhibit 05.06](#)).
- Specifications ([Exhibit 06.03](#) , [Exhibit 05.05](#)) .

Final design shall:

- Be relatable to the design input by documentation in sufficient detail to permit design verification.
- Specify required inspections and tests and include or reference appropriate acceptance criteria. Identify assemblies and /or components that are part of the item being designed.

5.4.3. Use of Computer programs for design analysis

Computer programs for design analysis shall:

- be tested prior to use them in accordance with [GP.05.09](#). Validation and Verification is documented in [Exhibit 05.21](#) where limitations are documented. Computer programs may be utilized without individual verification for each application if:
 - a) The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed, and
 - b) The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.
- be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer



DESIGN CONTROL

SECTION **05**

programs are made, verifications shall be required for evaluation of the effects in the previous validation and verification process.

- meet requirements of NQA-1, Part II, subpart 2.7 for the ones used for design & analysis.

The use of commercial grade dedicated computer programs is permitted. The process for dedication is described in [Section 8](#) of the QM. The process for dedication is described in [GP.08.20](#) and documented through a Validation and Verification report [Exhibit 05.21](#).

Computer programs found non-conforming shall require a corrective action in accordance with [Section 16](#) and review of design analysis performed with that version of the program.

Calculations shall be identifiable by subject (including structure, system, or component to which the calculation applies), originator, reviewer, and date; or by other data such that the calculations are retrievable.

5.4.4. Design Verification

Design verification provides assurance that final design is correct and satisfactory. The verification method shall be determined. Acceptable verification methods include, but are not limited to, any one or a combination of the following:

- design reviews
- alternate calculation
- qualification test

Design review and alternate calculations process are detailed in [GP.05.01](#) . Design verification shall:

- be performed by any competent individual(s) or group(s) other than those who performed the original design but who may be from the same organization. This verification may be performed by the originator's supervisor, provided the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design or, provided the supervisor is the only individual in the organization competent to perform the verification.
- for the level of design activity accomplished, be performed prior to release for procurement, manufacture and fabrication. In those cases where this timing cannot be met, such as when insufficient data exist, the unverified portion of the design shall be identified as incomplete. In all cases, the design verification shall be completed prior to stamping the item.
- Design verification is done by the performance of design reviews which may be supplemented by alternate calculations and qualification tests.

Evidence of design verification activities together with "Design Report" are maintained by "Design and Analysis Engineer" (see [Exhibit 05.12](#)).



DESIGN CONTROL

SECTION **05**

5.4.5. Design Reports

"Design and Analysis Engineer" shall provide a "Design Report" [Exhibit 05.31](#) for each component, containment or support. The drawing used for design and construction shall be identified and described in the "Design Report" before it is certified. Persons responsible for preparation, checking, review and approval of the "Design Report" are identified by name, signature and date on cover page of the "Design Report". The assigned "Design and Analysis Engineer" is responsible for filing the "Design Report".

5.4.6. -RESERVED-

5.4.7. Modification of Documents and Reconciliation with "Design Report"

Prior to commencing fabrication, IP shall verify the current edition of all documents utilized in the design including regulatory guides and licensing criteria to ensure there has been no modification to them.

Any modification to a document shall be reconciled with the "Design Report" by "Design and Analysis Engineer" and a revision or addenda shall be prepared and certified and filed with the "Design Report".

IP can submit a "Non-Conformance Report" (see [Exhibit 15.01](#)) or contract changes to "Design and Analysis Engineer" for reconciliation of "Design Report" and the modification of the design documents, as necessary. "Design Report" reconciliation and design document modification is documented either on a "Non-Conformance Report" [Exhibit 15.01](#) or on the "Work Order" [Exhibit 05.01](#) for contract changes by the JP.

A revision or addenda to the "Design Report" shall be prepared and, if required by Code or contract, certified to indicate the basis on which this has been accomplished. All such revised documentation shall be filed with the completed Design Report. Copies shall again be available to the customer.

"Product Design Technicians" from "Engineering and Projects" area shall prepare an "As-Built drawing" based on actual dimensions and configurations of the item. "Product Design Technician" provides the "As-Built drawing" to "Design and Analysis Engineer" for reconciliation of the "Design Report".

5.5. DESIGN DRAWINGS

5.5.1. Drawings containing and complying with the design (see [Exhibit 05.03](#), [Exhibit 05.24](#)) are prepared from contractual requirements by "Product Design Technician" or "Technical Office Technician" belonging to "Engineering & Projects" or "Service & Special Projects" areas respectively.

5.5.2. The method of drawings review is detailed in the procedure [GP.05.02.01](#), and provides for reviewing and approving is performed by individuals other than those who prepared the original drawing, after which they are signed off.

The drawings are submitted by using the document control system PLM by



DESIGN CONTROL

SECTION **05**

"Product Design Technician" for review by authorized individuals. Any comments are documented on the PLM system and returned to the originator. The comments are noted and implemented / incorporated into the drawing and the modified drawing resubmitted to the reviewers using the PLM system. When the reviewers are satisfied, their approval is documented with the electronic sign off and date in the relevant position of the drawing.

Drawings and changes thereto are performed the same manner as for the initial issue according to [GP.05.02.01](#) to assure correctness and to check that contractual requirements are met; they are approved and electronically signed off.

When required by contract, drawings are submitted to Customer for approval, through the JP. Evidence of review is documented in the PLM. The status of Customer approval is recorded in the PLM system.

5.6 SPECIFICATIONS AND CONSTRUCTION PROCEDURES

All information regarding methods of construction, technical requirements, material, testing, examination and quality standards are detailed in specifications (see, [Exhibit 06.03](#), [Exhibit 10.18](#), [Exhibit 06.09](#)) as described in [GP.05.03](#) and [GP.05.17](#).

The issuance of complementary engineering documents (see [Exhibit 05.05](#), [Exhibit 05.06](#), [Exhibit 05.13](#)) is described in [GP.05.13](#).

The specifications are submitted for review, by groups or individuals other than those who prepared the original specification through the PLM, prior to implementation. Any comments are documented in a comment section of PLM module or sent by other methods and returned to the originator. The comments are noted and implemented/incorporated by the originator into the specification and the modified specification resubmitted to the reviewers through PLM. When the reviewers are satisfied, their approval is documented with sign off and date in the relevant position of the specification. In addition, NDE specifications will be approved by the certified Level III in the applicable method.

When required by contract, specifications are submitted to Customer approval or information by JP, in accordance with [GP.07.01](#), using a document transmittal form (see [Exhibit 05.04](#)). The status of Customer approval and documental evidence are recorded in the PLM system.

5.7. CONTROLLED DOCUMENTS DISTRIBUTION

The controlled distribution of OT [Exhibit 05.01](#), drawings and specifications, is described in [Section 07](#) of this Manual "Document Control".

5.8. GRADE APPROACH

Once received the purchase order of the customer, it is analyzed the level of Important for Nuclear Safety (another terminology may be used in accordance with it is indicated by the customer ex.: important for the protection, safety related,..) defined by the customer or final user.

The different parts are classified by the designer, in case Ensa is the responsible of the



DESIGN CONTROL

SECTION **05**

design, it is defined in [SP.05.20](#). Requirements for manufacturing and control will be based on contractual requirements, manufacturing code, regulatory requirements according with the level of Importance for Nuclear Safety and they will be translated to manufacturing and control documentation. In [GP.05.36](#) it is describe different application of "grade approach" in Ensa activities.

In case it is required to define Important for Protection Activities, the applicable procedure is [SP.05.34](#).

REFERENCES

- [Exhibit 05.01](#) Work Order (OT)
- [Exhibit 05.03](#) Drawing
- [Exhibit 05.04](#) Document Transmittal Form
- [Exhibit 05.05](#) Complementary Engineering Document (DCI)
- [Exhibit 05.06](#) Engineering Complementary Drawing (PCI)
- [Exhibit 05.07](#) Work Request (RDT)
- [Exhibit 05.08](#) Risk Management Plan for project
- [Exhibit 05.09](#) Contractual Change Request
- [Exhibit 05.10](#) Design Review Action Item
- [Exhibit 05.11](#) Design Review Check List
- [Exhibit 05.12](#) Independent verification check list
- [Exhibit 05.13](#) Complementary Instruction (IC)
- [Exhibit 05.14](#) Analytical report
- [Exhibit 05.15](#) Design Input Review
- [Exhibit 05.16](#) Certifying Engineer Verification Checklist
- [Exhibit 05.20](#) List of software limitations
- [Exhibit 05.21](#) Validation - verification certificate
- [Exhibit 05.24](#) Business Development Drawing
- [Exhibit 05.25](#) EDS - Engineering Data Sheet
- [Exhibit 05.26](#) Design specification review according to NCA/WA
- [Exhibit 05.29](#) Construction specification review
- [Exhibit 05.30](#) Design drawings verification report
- [Exhibit 05.31](#) Design Report



SPECIFICATIONS, PROCEDURES AND DRAWINGS

SECTION **06**

- 6.0 PURPOSE
 - 6.1 SCOPE
 - 6.2 SPECIFICATIONS AND WELDING PROCEDURE SPECIFICATIONS
 - 6.3 GENERAL PROCEDURES
 - 6.4 SPECIFIC PROCEDURES
 - 6.5 PROJECT QUALITY PLANS
 - 6.6 COMPLEMENTARY INSTRUCTIONS
 - 6.7 MANUFACTURING DRAWINGS
 - 6.8. CALIBRATION AND TESTING LABORATORY PROCEDURES
 - 6.9 CTA DRAWINGS AND PROCEDURES
- REFERENCES



6.0. PURPOSE

To assure that activities affecting product quality are prescribed by clear and complete documented specifications, procedures and drawings.

6.1. SCOPE

All Ensa areas prepare and maintain at least the following written documents prescribing criteria and methods to perform activities affecting quality:

- Specifications and Welding Procedure Specification (WPS)
- General Procedures (GP)
- Specific Procedures (SP)
- Project Quality Plans (PQP)
- Complementary Instructions (IC)
- Drawings
- Calibration and testing Laboratory procedures

6.2. SPECIFICATIONS AND WELDING PROCEDURE SPECIFICATIONS

The specifications [Exhibit 06.03](#) and WPS [Exhibit 10.18](#) are prepared from the applicable contractual and Code requirements by "Documentation" and "Welding Development" units from "Engineering and Projects" and CTA areas respectively (see [Sections 05](#) and [Sections 10](#)), detailing the necessary parameters of work including quantitative and qualitative criteria. Review and approval are also identified in these sections.

The set of specifications issued for each contract, covers not less than the following activities:

- Nondestructive examinations.
- Materials.
- In-process controls, examination and testing.
- Thermal cutting.
- Heat treatments.
- Handling, storage, cleaning, preservation, shipping, etc...
- WPS and other specifications related to the welding field.

6.3. GENERAL PROCEDURES

GP [Exhibit 06.01-](#) are established as required for Ensa general activities accomplished by all areas; they describe the method to comply with the requirements of the QM. Responsibility of preparation, review and approval is outlined in the [GP.06.02](#), except GPs from Section "3" , they will be approved by the person in charge of the area or corresponding VP.

GP are numbered following this QM sections to whose activities they refer and apply to all contracts, if there is not specific mention to the contrary.

6.4 SPECIFIC PROCEDURES

The function of the SP is to document specific Customer requirements or regulatory ones affecting in a generic way to one or various contracts. The responsibility for the preparation, revision and approval is detailed in general procedure [GP.06.02](#), except SPs



from Section "3" , they will be approved by the person in charge of the area or corresponding VP.

SP are numbered according to the sections of this QM to which activities are referred and are applicable to the defined scope and documented in accordance with the [Exhibit 06.10](#)

6.5 PROJECT QUALITY PLAN

When contractually required, PQP documents the differences identified at comparing the Customer quality system requirements and Ensa Quality Program. However, they shall not negate the Ensa QM for Code items.

The PQP will be issued by the QAE assigned to the project, or also QAS in case of projects completely managed at subcontractors facilities, reviewed and approved by the QAM. The revision process of a PQP shall be performed the same way as the initial issue/previous revision.

PQP will be identified by AAAAQPYYY, being AAAA the contract number and YYY a sequential number and documented in accordance with the [Exhibit 06.11](#).

6.6. COMPLEMENTARY INSTRUCTIONS

IC [Exhibit 05.13](#) are internal written documents, prepared and maintained by the department responsible for its preparation, provides detailed manufacturing supplementary information for specific manufacturing and control operations.

The responsibility for the preparation, revision and approval is detailed in general procedure [GP.05.13](#).

6.7. MANUFACTURING DRAWINGS

Drawings containing and complying with the design (see [Exhibit 05.03](#), [Exhibit 05.06](#), [Exhibit 05.24](#)) are prepared from contractual requirements and design drawings by "Product Design Technicians" or "Technical Office Technicians" belonging to "Engineering & Projects" or "Services & Special Projects" respectively. The set of drawings issued for each contract covers as a minimum the following areas:

- General layout drawings.
- Material procurements drawings.
- Manufacturing drawings.
- As-Built drawings.

The method of drawings review is detailed in the procedure [GP.05.02.01](#), and provides for reviewing and approving is performed by individuals other than those who prepared the original drawing, after which they are signed off.

The drawings are submitted by using the document control system PLM by "Product Design Technicians" for review by authorized individuals. Any comments are documented on the PLM system and returned to the originator. The comments are noted and implemented / incorporated into the drawing and the modified drawing



SPECIFICATIONS, PROCEDURES AND DRAWINGS

SECTION **06**

resubmitted to the reviewers using the PLM system. When the reviewers are satisfied, their approval is documented with the electronic sign off and date in the relevant position of the drawing.

Drawings and changes thereto are performed the same manner as for the initial issue according to [GP.05.02.01](#) to assure correctness and to check that contractual requirements are met; they are approved and electronically signed off.

When required by contract, drawings are submitted to Customer for approval, through the JP. Evidence of review is documented in the PLM. The status of Customer approval is recorded in the PLM system.

6.8. CALIBRATION AND TESTING LABORATORY PROCEDURES

Procedures for calibration and testing [Exhibit 06.12](#) are prepared and maintained by "Calibration Laboratory" and "Testing Laboratory" managers to provide detailed supplementary information to accomplish their specific activities such as chemical, mechanical, metallographic analysis, qualification of welders and welding procedures and calibration of equipment.

6.9. CTA DRAWINGS AND PROCEDURES

CTA workshop will be managed through Laboratory Work Orders [Exhibit 06.04](#) issued by "Welding technicians" managed by GINLAB software. When necessary to detail the requirements to prepare CTA works, "Welding technicians" will issue documentation such as :drawings [Exhibit 06.09](#) , Tubing and tack expansion CTA [Exhibit 06.07](#) ,...

REFERENCES

- [Exhibit 06.01-](#) General Procedures Manual
- [Exhibit 06.02](#) Testing and sampling plan
- [Exhibit 06.03](#) Specification
- [Exhibit 06.04](#) Laboratory Work Order
- [Exhibit 06.07](#) Tubing and tack expansion CTA
- [Exhibit 06.09](#) Test samples drawing
- [Exhibit 06.10](#) Specific Procedures Manual
- [Exhibit 06.11](#) Project Quality Plan
- [Exhibit 06.12](#) Laboratory procedures



DOCUMENT CONTROL

SECTION **07**

7.0 PURPOSE

7.1 RESPONSIBILITIES

7.2 PROCEDURE

7.3 RECORD RETENTION RESPONSIBILITIES

7.4 COMPUTER PROGRAMS AFFECTED BY THE QUALITY SYSTEM

REFERENCES



7.0. PURPOSE

To provide measures to control the issuance and disposition of documents such as specifications, procedures, drawings and computer programs which prescribe activities affecting quality.

To define measures which assure that documents and computer programs, including changes, other than design analysis programs, are reviewed for adequacy and released by authorized personnel and distributed to and used at the location where the prescribed activity is performed.

To provide procedures which assure that the latest applicable drawings and specifications required by Code and Design Specifications, are used for manufacturing, installation, examination and testing.

7.1. RESPONSIBILITIES

7.1.1. Responsibilities for the preparation, review, approval and issuance of Ensa, Customer and Vendor documents are treated in the different sections of this Manual.

7.1.2. Distribution of Customer contractual documents through the PLM System is per [Section 05](#) of this Manual.

Distribution of Vendor submittals is per [GP.08.01](#): "Purchasing of Materials, Parts or Subcontracting" and [Section 08](#) of this Manual.

The distribution and control of documentation is performed through the PLM that provides the applicable documentation to the application "Control de Procesos" for works in the shop. "Documentation Distribution Officer" (ODD), reporting to "Engineering and Projects" is responsible for the distribution and control of the documentation in the event that the electronic system is down.

7.1.3. "Digital Transformation and Information Technology Systems manager" is responsible for providing usernames and initial passwords to access to Ensa applications. Individual's Managers defines the authorizations to perform activities in the computer systems for that individual and the personal password ensures the identity of the individual.

7.2 PROCEDURE

7.2.1 The reference document used for the planning of documents directly related with the design and construction is the IPS originated by "Planning Technicians" to assure that, for a given contract, all documents pertaining to activities related to design, procurement, engineering, manufacturing and quality are planned. IPS must contain the minimum following information:

- Ensa Project code
- List of the main activities of the project
- Scheduled Start date



DOCUMENT CONTROL

SECTION **07**

- Scheduled Finish date
- Duration of the activity (days)

7.2.2. All users are authorized to consult the IPS. All users will have access to the latest revision of the documents as indicated in the PLM. In this way, all concerned personnel will make sure that the documents they are using are valid and in the current revision.

7.2.3. The [GP.07.01](#) describes in detail the document control system used by Ensa. Only documents issued on a controlled distribution basis shall be used in construction or design activities.

Distribution authorization is given by the originator in the PLM for documents to be distributed electronically. When documents must be distributed on paper (e.g.: the system is down), ODD shall perform the distribution by using hard copy documents reach the assigned destination together with the "Distribution Authorization form" (see [Exhibit 07.02](#) and [Exhibit 07.06](#)).

In this case, all controlled paper documents are red stamped "Controlled Distribution" to indicate validity. "Controlled Distribution" mark on the document must contain the following minimum information:

- "Controlled Copy" identification
- Date of distribution

In case a document is distributed with limitations (ex: approved with comments, waiver to proceed at risk [Exhibit 07.13](#). "Deviation Stamp" mark on the cover page of the document must contain the following minimum information:

- "Deviation Copy" identification
- Section of "Valid within shown limits" (identified in the document) or "Meets the comments transmitted in" plus the reference of the document.
- Date of distribution

Paper copies taken through the application "Control de Procesos" in the shop may be used to facilitate reading and consultation of requirements during job process, provided the revision and identification of the document is checked in the electronic system available in the workshop before starting that activity. It shall be managed through the controls described in [GP.07.01](#).

7.2.4. When a document (specification, procedure or drawing) is found to be in error and affects the items under construction, "Quality Control"(QC) shall be verbally notified and QC shall stop the work and decide whether work may continue if the document error does not affect the operation being performed. QC shall hold that operation and notify the unit affected about the erroneous part of the document for resolution. The details for this procedure are contained in [GP.07.01](#).

Prior to proceeding beyond the hold point, a revised and approved document must be prepared and distributed in a controlled manner.



DOCUMENT CONTROL

SECTION **07**

7.2.5 Changes in documents are handled in the same manner as the original version.

7.3. RECORD RETENTION RESPONSIBILITIES

Every originator of documents is responsible for retaining such document and revisions in the PLM, Intranet, SIDOCO or Ensa CDP.

Documents retained by QA are those described in [Section 18](#) of this Manual.

7.4. COMPUTER PROGRAMS AFFECTED BY THE QUALITY SYSTEM

Prior to use computer programs, other than design analysis, that affected by the Quality System shall be tested to verify conformance to specified requirements. Detailed procedure for this activity and records maintenance are included in [GP.07.06](#). Verification and validation is documented (see [Exhibit 07.11](#)).

Computer systems used for activities affecting quality shall be access controlled by password.

REFERENCES

- [Exhibit 07.02](#) Distribution authorization
- [Exhibit 07.06](#) Instructions for filling the Distribution
- [Exhibit 07.11](#) Validation - verification certificate of computer applications
- [Exhibit 07.13](#) Waiver to proceed at risk



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION **08**

- 8.0 PURPOSE
 - 8.1 PROCUREMENT PLANNING AND CONTROL OF MATERIAL PROCUREMENT DOCUMENT
 - 8.2 VENDOR SURVEYS
 - 8.3 SOURCE INSPECTION
 - 8.4 RECEIVING INSPECTION
 - 8.5 CUSTOMER SUPPLIED MATERIALS
 - 8.6 UNASSIGNED MATERIAL
 - 8.7 ITEMS IDENTIFICATION
 - 8.8 CERTIFICATION OF MATERIAL BY ENSA
 - 8.9 UNQUALIFIED SOURCE MATERIAL
 - 8.10 SUBCONTRACTING OF BENDING AND FORMING
 - 8.11 SUBCONTRACTING CALIBRATION AND TESTING SERVICES
 - 8.12 WELDING GASES
- REFERENCES



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION 08

8.0. PURPOSE

To define and implement a system to control procurement of material, items and subcontracted services assuring compliance with Code and contractual documents.

To establish the measures to assure traceability, source evaluation, examinations at source and reception to provide objective evidence of quality.

8.1. PROCUREMENT PLANNING AND CONTROL OF MATERIAL PROCUREMENT DOCUMENTS

8.1.1. Based on Design & Analysis documents, the output of Design Process, IP defines material, items and services requirements in Procurement Request (PR) the minimum following information:

- PR identification code and revision
- Category of the procurement request
- description of the item requested
- number of units requested
- delivery date
- applicable documentation
- observations
- quality codes for subcontractor selection
- quality requirements (SQAR [Exhibit 08.16](#), additional vendor quality requirements, if necessary)

Preparation, review and approval of specifications and drawings needed for procurement, is per [Section 05](#).

8.1.2. Before any procurement activities start, taking into account the definitions of materials and the planned purchasing activities in the IPS, PR for the material, item or service is prepared, review and approved in accordance with [GP.08.01](#). In case of needed, a "Purchasing Specification" is issue by "Documentation Engineer" from "Engineering and Projects" in accordance with [GP.05.03](#).

8.1.3. The PR includes the technical requirements , including references of applicable documents and revisions, and quality requirements (Supplier Quality Assurance Requirements (SQAR) [Exhibit 08.16](#)) as described in [GP.08.01](#). Procurement activity is categorized in accordance with [GP.08.08](#). By means of the information included in the PR, Ensa extends all applicable requirements and controls to all their Vendors.

It will be also indicated the documents requested to the Supplier. When required, the Vendors' document to be approved is stamped with "Approved", "Not approved", or "Approved with Comments" on the cover page of the document.

PR is approved by "Supply Control" (QAS), this approval triggers the procurement action.



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION **08**

For general services non assigned to a specific contract (ex: calibration, audits to suppliers, design & analysis computer programs, etc...), a Requirement Voucher (VN) may be an alternative to the PR, as described in [GP.08.01](#). VN must contain the following minimum information:

- VN identification code and revision
- description of the item requested
- number of units requested
- delivery date
- applicable documentation
- observations
- quality codes for subcontractor selection, if affected by quality

It is allowed the procurement of commercial design & analysis computer programs, they are under the provisions of the [GP.08.20](#) of commercial grade dedication (see [Exhibit 08.24](#)). Its evaluation and acceptance will be documented with a Validation and verification report [Exhibit 05.21](#).

8.1.4. -Reserved –

8.1.5. Bids are evaluated by "Procurement technician", taking into consideration technical and quality requirements, various potential Vendors and their capabilities. "Procurement technician" selects the successful bidder from the Qualified Vendors List (QVL) system management. QVL must contain the following minimum information:

- Supplier code.
- Supplier location information.
- Supplier qualification codes.
- Maximum date of supplier qualification codes.
- Description of supplier qualification codes.

Once selected the supplier, "Procurement technician" issues the PO. PO must contain the following minimum information:

- PO identification code and revision
- Supplier name.
- Supplier location information.
- Technical and quality requirements
- Delivery conditions.

Technical and quality requirements identified in the PR are directly translated to the PO without "Procurement technician" intervention.

Prior to issuance of the PO, "Procurement technician" shall resolve any discrepancy or contingency affecting quality and document agreements reached in the PO or in its accompanying cover letter. Copies of all PO are available through Ensa Intranet.

In order to reduce the introduction of possible counterfeit, fraudulent or suspect

CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

items, procedure GP 15.16 gives instructions about the selection of providers, specific information when a purchase order is issued, control of products and services and monitoring and measuring of activities.

8.1.6. In the event that changes are requested to be implemented, the Vendor is informed of the needed change through a new revision of the PO.

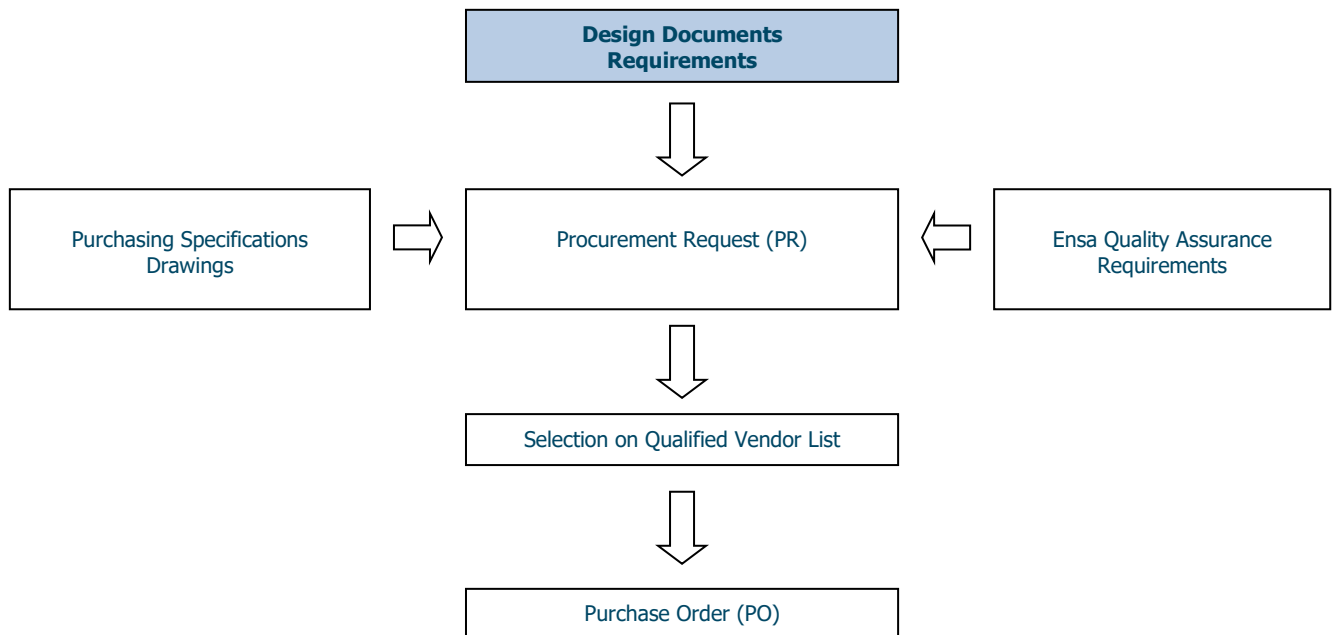
8.1.7 Welding Material

Before any procurement for welding material, taking into account the definitions of materials based on requirements and welding procedure qualifications (PQR), "Welding List" is prepared following [GP.10.13](#), which is the basic planning document to schedule all welding activities and to prepare procurement activities through the PR of each filler material defined in the WPS.

Following receiving inspection, the allocation of qualified material to specific contracts is responsibility of "Welding technicians".

8.1.8. Assessment of the service of the supplier is record in Procurement management system in accordance with [GP.08.07](#).

8.1.9 An illustration of the Procurement Process for Base Material and Services is shown below:



8.2. VENDOR SURVEYS

8.2.1. The procurement of material, items and services is from Qualified Vendors in accordance with defined basis [GP.08.06](#), in case a survey is requested, it is performed in accordance with [GP.08.03](#). Qualified Vendors are included in a database.



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

8.2.1. Vendor Survey Process

Lead Auditor will obtain a copy of the prospective vendor's Quality Assurance Manual and review it for adequacy in meeting Code and Ensa requirements. If acceptable, the Lead Auditor shall use this as a guide to prepare the survey that includes the review the implementation of the program at the location of the work.

If requested, a survey is performed by a team selected by QAM. Each survey shall be led by a qualified Lead Auditor in accordance with [Section 02](#) of this QM. Lead Auditor shall prepare the Audit Plan (see [Exhibit 08.36](#)) with the team.

Audit report (see [Exhibit 08.04](#)), check list, used for verification, and evidence issued by Lead Auditor are formally reported and reviewed by QAM. When necessary, corrective action (see [Exhibit 16.01](#)) is taken as necessary with Vendor representatives and controlled by QAS. All survey records are retained by "Supply Control".

8.2.2. - Reserved-.

8.2.3. - Reserved-. .

8.2.4. - Reserved-. .

8.2.5. - Reserved-. .

8.2.6. QAS updates the QVL for including new qualified Vendors and/or for eliminating unsatisfactory sources of supply each time a Vendor status changes. QVL may be consulted on the intranet application LA30.

8.2.7 Evaluation for inclusion or removal from the QVL of Vendors of Non-Code and non-safety related materials, items or services is based on any or all of the following methods:

- An industrially accepted standard (e.g. ISO-9001).
- Review of Vendor history of providing similar products.
- Review of information in existing Vendor quality records.
- Direct evaluation of Vendor facilities, to assess its technical and quality capabilities.

Methods and references used for evaluation are referenced in Qualification Report (I.L) (See [Exhibit 08.14](#)).

8.3. SOURCE INSPECTION

8.3.1. The inspection point plan, traveler or equivalent Vendor document, specifies manufacturing, test and examination operations, applicable documents and Ensa and other organizations inspection points and certification to be provided. Supplier will inform different parties through written notification (see [Exhibit](#)



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION **08**

[08.35](#)).

8.3.2. If testing must be completed at Ensa, the complete sequence of examinations and test to be performed on any item are established in the Material Inspection Plan (MIP) (see [Exhibit 08.12](#)), prepared by "Documentation", reviewed by QAS and approved by IP. It is formalized through a Testing Request (SE) (see [Exhibit 08.32](#)).

8.3.3. Source inspection is performed, as needed, by an Ensa Quality representative, qualified as per procedure [GP.02.01](#) and/or by a qualified inspector belonging to a supplier of services qualified by Ensa and documented by Source Inspection Report [Exhibit 08.05](#) available through the PLM.
Source inspection includes witnessing intermediate and/or final testing, review of vendor certification/ records and Certificate of Compliance.
The Source Inspector detecting or being informed of a non-conformity may instruct the vendor to stop work until resolution of the condition adverse to quality and the vendor to manage such situation in accordance with their Corrective Action or Non Conformance program.

8.3.4 Any item found at Vendor's location to be in non-conformance with the requirement of the procurement documents, is held for disposition at Vendors.

Ensa, through the PR, requires the Vendor to submit reports documenting the non-conformities. Nonconformities with identification to the following situations will at least be submitted for Ensa approval:

- Technical or material requirements are not met.
- Requirements established in contractual documents already approved by Ensa and are not met.
- Non conformities which cannot be corrected by continuation of the original fabrication process or by rework.
- The item does not comply with the original requirements although such item has led to a condition in which the capacity of the item to perform its function is not affected.

In this case, Ensa issues the NCR in the Ensa system, referencing the Supplier documentation related with the supplier NCR for Ensa disposition. Such Non-Conformities are handled according to [Section 15](#) of this Manual.

If a repair is approved, the item is re-inspected by the Ensa Source Inspector when so designated by QAS on the disposition of the nonconformance report. Weld repairs shall only be performed by Ensa or by MO when permitted by the material specification and included in their QA Program.

If the repair cannot be performed at Vendor Shop, the repair procedure is prepared and approved by Ensa and performed in Ensa shop.



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

8.4. RECEIVING INSPECTION

8.4.1. QAS make available through the PLM a controlled copy of all procurement documents defining the material requirements and the when Source Inspection was performed.

8.4.2. [GP.08.02](#) describes in detail the receiving inspection activities for base material and parts. Welding material receiving inspection is described in [Section 10](#) of this Manual.

When the material arrives at Ensa, "Warehouse operators" examine the material for configuration, damage and cleanliness and prepare a Receiving Inspection Notice (MR) . MR must contain the following minimum information:

- MR identification code and revision
- PR code related to this reception
- PO code related to this reception
- Item received
- Quantity ordered
- Quantity received
- Lot/ batch of base or filler metal
- Warehouse location
- Markings on the materials

The status of the material received is performed through tags (see [Exhibit 08.10](#)). For miscellaneous items which must be kept in specific containers, boxes, etc...due to the size, number (e.g.: washers, nuts...), "Warehouse operators" may stick, upon receipt and release of the IR/SR through the Intranet, an identification tag (see [Exhibit 08.10](#)) in order to facilitate the traceability of those items.

If the material is scrapped, a red label shall be placed on the item and segregated when feasible, in accordance with [Section 15](#) for handling on Non Conformance material.

In the event that material must be directly delivered from the Vendor to another Ensa's subcontractor, the latter will issue the reception control and notify Ensa to ask for evidences of the reception to issue the MR.

8.4.3. The MR is then sent, through the Intranet, to QAS who verifies the marking in accordance with the material specification and vendor certification for acceptability After review and acceptance by QAS of the Vendor Certification, QAS issues the Receiving Inspection Report Base Material Receiving Inspection Report (IR) or Welding material receiving inspection report (SR) in Procurement Management System.

IR must contain the following minimum information:

- IR identification code and revision
- PR code related to this reception



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

- PO code related to this reception
- MR code related to this reception
- Item received
- Quantity received
- Lot/ batch/Heat of base metal
- Certificate reference
- Markings on the materials
- Certification is attached.

SR must contain the following minimum information:

- SR identification code and revision
- PR code related to this reception
- PO code related to this reception
- MR code related to this reception
- Item received
- Procurement specification
- Quantity received
- Lot/ batch/Heat of filler metal
- References of test performed in Ensa
- Certificate reference
- Certification is attached.

Items requiring Certification Marking by the Code and further used for shop or field assembly and installation shall be controlled by QAS by reviewing the applicable Data Report and checking the stamped item.

Services are accepted, based on satisfactory review of objective evidence for conformance to procurement requirements.

This report will be reviewed and approved by a QAS different from the author, releasing the incoming item for storage or fabrication in the intranet system. QC verifies the status of the item in the intranet prior to sign off the reception operation in the IPP.

The procedure for handling nonconforming items discovered during receiving inspection is detailed in [Section 15](#) of this Manual. Vendors are informed accordingly by "Procurement technicians".

In order to reduce the introduction of possible counterfeit, fraudulent or suspect items, procedure GP 15.16 gives instructions about the reception control.

8.4.4 Once the material is accepted, QC may remove the tags to proceed with manufacturing activities. Once the item is unpacked, QC is responsible to verify the marks of the part versus what it is identified in the IR and a general visual inspection for the absence of any damage.

8.5 CUSTOMER SUPPLIED MATERIALS



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION **08**

Material may be supplied by the Customer who has got final responsibility for the component being constructed. This material is denominated "Free-issue". The material is examined for shipping damage and identification and reported on the MR.

QAS shall review the release documentation showing the customer acceptance of the material (stamps, certification, etc...) and verify the marking of the material for correctness and traceability to the documentation. Acceptance is indicated on an IR/SR.

When the customer, a certificate holder, is going to stamp the item to be fabricated, assembled or installed, may furnish Ensa material and Ensa is not required to ask for its Quality System Certificate not to perform a survey, qualify or audit the customer.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

8.6 UNASSIGNED MATERIAL

When material was not specifically procured for the job where it is intended to be used (material in inventory) the following steps will be taken:

- a) IP will identify the requirements that the item should meet in the form Unassigned Material Request (UM) in Procurement Management System.
- b) QAS will review and approve the material and existing certification in accordance with the requirements identified in the UM through the issuance of a IR/SR.
- c) If the material can meet the requirements of the new contract with further tests, these shall be identified on the UM.

UM must contain the following minimum information:

- UM identification code and revision
- IR/SR code related to this request
- PO code related to this request
- Item requested
- Quantity requested
- Lot/ batch/Heat of base/filler metal requested
- Applicable specification

8.7. ITEMS IDENTIFICATION

8.7.1. All items must arrive at Ensa identified in accordance with procurement documentation. QAS maintains through the Intranet the items received, identifying heat nº, PO nº., PR no., item nº, (and serial nº for identical items) Vendor name and IR/SR number.

8.7.2. In case of cutting of material, "Marking personnel", prior to cutting, reapply item and serial number to each piece, whenever it is possible.



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

In case of machining, transfer of the markings will be performed prior to start of the machining operation. If temporary marking has to be used, the final marking shall be applied immediately after availability of the piece.

A coded marking may be used with the concurrence of the TPI/NB/Customer. Marking transfer operation is recorded in the IPP when this operation is included in it by QC.

When due to space limitation, part or all the marking cannot be performed directly on the piece(s), containers tagged with the necessary identification shall be used for handling the items till installation or use.

- 8.7.3. The method of marking shall not result in any harmful contamination or sharp discontinuities and the marking shall identify the material until the component is assembled. Marking locations shall be in areas that will not interfere with the function or quality aspects of the item.

Stamping, when used, shall be done with blunt nosed continuous or blunt-nosed interrupted-dot die stamps.

8.8. CERTIFICATION OF MATERIAL BY ENSA

- 8.8.1 When material has been produced in accordance with NCA-3800 and any operation has not been performed (or certified) by MO, Ensa will complete or subcontract the missing operation through a MIP.
- 8.8.2 Upon MIP completion, a CMTR [Exhibit 08.37](#) is prepared for the operations performed by Ensa or subcontractors. The CMTR will certify that the contents of the report are correct and accurate and that all test results and operations performed by Ensa or subcontractors, are in compliance with the requirements of the material specification. The CMTR will describe the material identification including material designation, heat or lot number and item number.
- 8.8.3 Once Ensa CMTR is available, QAS release the material issuing the IR/SR as described in paragraph 8.4.4. Ensa CMTR will be filed together with Vendor CMTR. This activity shall include conversion of materials in Code Classes. The Ensa CMTR shall also include the MO CMTR as an identified attachment.
- 8.8.4 For welding materials (NCA-1221.2, WA-1223) only, when permitted by the material specification and the rules of this Section [NB/NC/ND/NE/NF/NG-2400, NH-2121(g), CC-2600, WB/WC-2400], the MO or Certificate Holder may provide a chemical analysis of the welding material in lieu of furnishing the melting mill heat analysis. When operations other than chemical analysis, heat treatment, tests, examination, or repairs that require maintenance of traceability are subcontracted, these operations and the approved suppliers performing them shall be listed on the CMTR, or the approved suppliers certification for the operation may be furnished as an attachment to the CMTR.



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION **08**

8.8.5 When a material is certified in accordance with a Code Edition, and need to be certified against another Code Edition, different from those already certified, ENSA is not acting as MO.

QAS shall issue a new CMTR after reviewing and verifying that the applicable Code Edition and Addenda requirements are met indicating that it is a Conformity Assessment.

8.9. -RESERVED-

8.10. SUBCONTRACTING OF BENDING AND FORMING

8.10.1. Bending and forming services are subcontracted by Ensa in accordance with the requirements of this Section. These services are outside of MO scope and they are manufacturing operations.

8.10.2. In the PR, it is indicated the requirements for process qualification, if applicable according to code requirements. PR will also define directly or by reference to drawings, the applicable forming/bending tolerances.

8.10.3. Forming and bending processes, where subsequent tack welding is involved, will only be subcontracted with appropriate Certificate of Authorization Holders.

8.10.4. Forming and bending processes of pressure barrier will be managed as a special process:

- using qualified procedures
- by qualified personnel.
- controlled by procedures with requirements of qualification of equipment, specified environment, calibration requirements, if necessary, and acceptance criteria.
- IPP or travelers will be used for process control.

8.11. SUBCONTRACTING CALIBRATION AND TESTING SERVICES

As alternative to a survey of calibration and testing services suppliers is applicable to Ensa, other Certificate Holders and/or Material Organizations. These organizations may accept, as an alternative to survey and audit, the accreditation by accrediting bodies recognized by International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).

These procedures are recorded in [Exhibit 08.21](#) for calibration and [Exhibit 08.23](#) for testing services.

NOTE:

The provisions of this section are considered a "Commercial Grade Dedication process".

8.12. WELDING GASES

Even welding gases are not specifically procured for the job where it is intended to be used (material in inventory), welding gases are purchased in accordance with pre-



CONTROL OF PURCHASED MATERIALS, ITEMS AND SERVICES

SECTION **08**

established procurement specifications/requirements under the generic contract 0GS2.

All bottles are identified with a color coding which identifies gas type and/or gas mixture against a specific color. Identification of bottle is maintained during storage.

REFERENCES

Exhibit 08.04	Audit Report
Exhibit 08.05	Source Inspection Report
Exhibit 08.10	Material receiving control labels
Exhibit 08.12	Material Inspection Plan (MIP)
Exhibit 08.14	Qualification Report
Exhibit 08.16	Suppliers Quality Assurance Requirements (SQAR)
Exhibit 08.21	Commercial dedication of calibration services
Exhibit 08.23	Commercial dedication of testing services
Exhibit 08.24	Commercial Grade design and analysis computer programs plan
Exhibit 08.31	Quality Engineering Data Sheet (QEDS)
Exhibit 08.32	Testing request (SE)
Exhibit 08.35	Suppliers witness and hold points notification
Exhibit 08.36	Audit Plan
Exhibit 08.37	Certified Material Test Report (CMTR)



PROCESS CONTROL

SECTION **09**

- 9.0 PURPOSE
 - 9.1 CONTROL OF OPERATIONS
 - 9.2 PREPARATION OF THE IPP
 - 9.3 INSPECTION AND EXAMINATIONS
 - 9.4 TESTING
 - 9.5 - RESERVED- T
 - 9.6 - RESERVED-
 - 9.7 SHIPPING RELEASE
 - 9.8 ENVIROMENT FOR THE OPERATIONS OF PROCESSES
- REFERENCES



PROCESS CONTROL

SECTION 09

9.0. PURPOSE

To describe the system to assure that processes affecting quality of materials, source materials or services are controlled through travellers, drawings, specifications, procedures or similar providing traceability for the manufacturing process.

Acceptance criteria shall be specified or referenced in the applicable document. Preparation, review and approval of the above documents, is as per [Section 05](#) and [06](#) of this QM. Distribution is as per [Section 07](#).

9.1. CONTROL OF OPERATIONS

The traveller used for process control is the "Inspection Point Plan" (IPP [Exhibit 09.01](#)), that includes all manufacturing, testing and examination activities required for the construction and service. It is complemented by internal operations related to the manufacturing such as handling, movements or internal controls. All operations are collected in the document "Hoja de Ruta / Route Sheet" (IPP/HR [Exhibit 09.02](#)).

The IPP controls the contractual examinations, processes and inspection status for the item being constructed. Evidences of inspection status, examination and control of process are identified by signature and date of individuals in the operation performed, indicating the result (Ex: Conform or Non-Conform).

The IPP provides space for reporting results, signature and date of Ensa, Regulatory Body, Notified Body, Third Party Inspection and/or Customer activities which were designated. Regulatory Body, Notified Body, Third Party Inspection and/or Customer signatures are required on the IPP against each hold point and each operation witnessed and/or reviewed. Signature, date and comments are entered into the IPP through the application "Control de Procesos" by logging the username and password.

Work shall not proceed beyond hold points without the signature and date or written consent of the designator is provided. Notifications for such operations shall be performed sufficiently in advance to allow arrangements for attendance.

Distribution

The IPP/HR are available through computer terminals available at the work stations in the shop. Each individual has a unique username and password to access the application "Control de Procesos".

QC have to make sure that all operations with inspection requirements (See [GP.09.01](#), P and C codes) are duly signed off and that the numbers of certificates and records produced are entered in the corresponding block.

Operation Execution

Special Processes are performed by qualified personnel in accordance with [GP.02.09](#), [GP.12.01](#) or specific provisions defined in the IPP such as specific personnel qualification and/or specific controls to verify absence of defects, compliance with contractual requirements, etc... [Sections 10](#), [11](#) and [12](#) provide more details for control of Welding, Heat Treatment and NDE processes specifically.

Hydraulic expansion of tubes is considered a special process and will be documented



with [Exhibit 10.08](#).

Each inspection operation, including welding materials, welding performance and procedure qualifications controls, is signed off by the "Quality Control personnel" (END or CODI inspectors or Quality Controllers) upon satisfactory acceptance. Welding operations are signed by the "Welding Foreman" after satisfactory completion and inclusion of the Welding Report identification (WR, [Exhibit 10.11](#) [Exhibit 10.09](#) [Exhibit 10.12](#) [Exhibit 10.03](#) [Exhibit 10.02](#)). The complete IPP, signed and dated with all corresponding certificates and reports provides objective evidence of inspection and examination operation. Certification of quality inspection operations will be certified through the application "Ensa CDP".

Once IPP is complete, QC is responsible to send the IPP to "Data Book" with all generated records with the exception of those performed with the software Ensa CDP. "Data Book" will print all out to build the Data Report and checks completeness and correctness of the documentation as required by [Section 18](#).

Independent Monitoring

Independent monitoring of operation may be performed by "Patrol Inspectors" qualified in accordance with [GP.02.01](#) in order to check compliance with requirements in the applicable documentation of the operation of the IPP. It is documented through "Patrol Inspection Records" such as [Exhibit 09.14](#) [Exhibit 09.15](#) [Exhibit 09.16](#) [Exhibit 09.17](#) or similar.

9.2. PREPARATION OF THE IPP

[GP.09.01](#) details the method used at Ensa for preparation, review and approval of the IPP.

- 9.2.1. "Methods engineer" prepares and reviews the IPP/HR describing manufacturing and inspection and test sequence in discrete sections, indicating those where certification is required by using the Ensa certification codes P or C.

The input data includes the applicable documents against each operation. The revision of applicable documents is updated by the application "Control de Procesos" (see [Section 07](#) of this Manual).

- 9.2.2 QAE select the operations of the IPP/HR to be included in the IPP and checks that all inspections and test operations are correctly addressed and approves it. IPP shall be submitted to customer for review and identification of inspection points prior to the starting of fabrication or installation, if requested.

IPP shall be submitted, as required, to Regulatory Body, Notified Body, Third Party Inspection or Customer as requested for review and selection of inspection points prior to the starting of fabrication or installation. Evidences of review of Regulatory Body, Notified Body or Third Party Inspection are kept by QAE.

Upon return of the IPP, Regulatory Body, Notified Body, Third Party Inspection and/or the Customer, as required, their requirements are incorporated by "Methods Engineer" or QAE in the final IPP.



PROCESS CONTROL

SECTION **09**

Changes in the sequence of operations or in the IPP/HR must be handled in accordance with [GP.09.01](#). "Methods Engineer" will review the IPP/HR in order to add an operation for information to explain the sequence changes on the related IPP/HR in the operations to be cancelled and in the operation to be added. Revisions to the IPP are treated in the same manner as the original document.

- 9.2.3 The approved IPP is distributed to the workshop by "Methods Engineer" through the application "Hoja de Ruta".
In the case of a revision of the IPP, each operation shall identify the new revision but for operations already performed the new revision shall show, in the column "ARV", the applicable revision of the IPP when the operation was performed. The content of that operation shall be the one corresponding to applicable revision of the IPP when the operation was performed.
- 9.2.4 Preparation operations such as Pre-Jobs [Exhibit 09.06](#) and return of experience operations such as Post-Jobs [Exhibit 09.08](#) will be included in as internal operations in the HR.

9.3. INSPECTION AND EXAMINATIONS

- 9.3.1. Inspection is performed by QC Inspectors and Quality Controllers qualified in accordance with with [GP.02.09](#) , [GP.12.01](#).
Inspections by persons during on-the-job training for qualification shall be performed under the direct observation and supervision of a qualified person and verification of conformance shall be by the qualified person until certification is achieved.
- 9.3.2. Final inspection shall include a record review of Non-Conformities identified in prior inspections to assure that they have been closed.
- 9.3.3. Inspection records shall, as a minimum, identify (a) through (h) below and is kept with the IPP:
1. Item inspected.
 2. Date of inspection.
 3. QC Inspector/Quality Controller.
 4. Type of inspection.
 5. Document and revision number used.
 6. Results of acceptability.
 7. Reference to Non-Conformity , in case of non-conformance result.
 8. Gage or instrument used.
- 9.3.4 Records for NDT are described in Section 12. Following examination records covers:
- [Exhibit 12.07](#) Dimensional control
 - [Exhibit 12.01](#) Miscellaneous Controls

9.4. TESTING

- 9.4.1. Testing to ensure the compliance of components or parts may be of different types (Ex: pressure test, functional, pre-operational test, set-up or installation).
Testing of component or parts is performed in accordance with written test specifications and is witnessed by QC, Regulatory Body, Notified Body, Third Party Inspection, Customer and any other representatives as required by the contract.

PROCESS CONTROLSECTION **09**

Testing specifications shall include or reference testing objectives and provisions for assuring that prerequisites for the given test have been met, that adequate instrumentation is available and used, that necessary monitoring is performed, and that suitable environmental conditions are maintained.

Prerequisites shall include the following, as applicable: calibrated instrumentation, appropriate equipment, certified personnel, condition of testing equipment and the item to be tested, suitable environmental conditions, and provisions for data acquisition, according to applicable specification.

In case of sampling is used to verify the compliance of a group of elements, sampling procedure will be inside applicable specification and it will be based on recognised standards or the criteria must be justified according the size of the simple and sampling method.

9.4.2. QC verifies that pressure gauges are calibrated, prior to each test or series of tests as defined in the Code. Pressure gauges are calibrated in accordance with [Section 14](#) of this Manual.

9.4.3. Test results shall be documented by QC qualified in accordance with [Section 02](#) of this Manual. Test records shall, as a minimum, identify (a) through (h) below:

- 1) Item tested;
- 2) Date of test;
- 3) Identification of test gages and data recorder equipment serial no.
- 4) Type of test;
- 5) Results and acceptability;
- 6) Action taken in connection with any deviations noted.
- 7) Person evaluating test results;
- 8) Specification number and revision.

In case of hydrostatic test, it is recorded with [Exhibit 12.06](#).

9.5. -RESERVED-**9.6. -RESERVED-****9.7. SHIPPING RELEASE**

Items are released for shipping, following the stamping of components, parts or appurtenances or final acceptance of materials by using the Shipping Release ([Exhibit 13.01](#)). This document is prepared by QC and approved by QAE.

9.8. ENVIROMENT FOR THE OPERATON OF PROCESSES

ENSA has implemented a health and safety management system to provide the necessary environment of its processes to achieve conformity of the products and services and to provide to the workers of a suitable environment considering physical factors.



PROCESS CONTROL

SECTION **09**

Inside the Nuclear Safety Culture, it is promoted a non-blaming attitude to protect workers and to promote question attitude for improvement and for the prompt detection of defects.

Cleanliness is a special physical factor and in certain cases required for the development of the processes.

REFERENCES

- [Exhibit 09.01](#) Plan de Puntos de Inspección (IPP) - Inspection Point Plan (PPI)
- [Exhibit 09.02](#) Hoja de Ruta / Route Sheet
- [Exhibit 09.04](#) Name Plate
- [Exhibit 09.05](#) Certificado de preparación de readiness reviews / Readiness Review Certificate Form
- [Exhibit 09.06](#) Check list para Pre-Jobs / Check list Pre-jobs
- [Exhibit 09.08](#) Check list para Post-jobs / Check lists para post-jobs
- [Exhibit 09.11](#) Acta reunión RTL / Launching Technical Meeting format
- [Exhibit 09.14](#) Registro Patrulla de Soldadura / Welding Patrol Surveillance Record
- [Exhibit 09.15](#) Registro Patrulla PT / PT Patrol Surveillance Record
- [Exhibit 09.16](#) Registro Patrulla MT / MT Patrol Surveillance Record
- [Exhibit 09.17](#) Registros Patrulla UT / UT Patrol Surveillance Record
- [Exhibit 12.06](#) Hydrostatic Test Certificate
- [Exhibit 12.01](#) Miscellaneous Controls
- [Exhibit 12.07](#) Dimensional Certificate



WELDING

SECTION **10**

10.0 PURPOSE

10.1 WELDING PROCEDURE QUALIFICATIONS

10.2 WELDER AND WELDING OPERATOR PERFORMANCE
QUALIFICATIONS

10.3 RECEIVING INSPECTION AND ACCEPTANCE

10.4 STORAGE, CONDITIONING AND TRACEABILITY

10.5 ASSIGNMENT OF WELDING MATERIAL DISTRIBUTION

10.5 ASSIGNMENT OF WELDERS

10.7 WELDING MATERIAL DISTRIBUTION

10.8 WELDING MONITORING

10.9 WELDING RECORD

REFERENCES



WELDING

SECTION 10

10.0. PURPOSE

This section describes the control system employed by Ensa to assure that all welding materials, procedures and personnel qualifications are in compliance with the requirements and contractual requirements.

10.1. WELDING PROCEDURE QUALIFICATIONS

10.1.1. As already described in [Section 8](#) and defined in [GP.10.13](#), for each contract, a "Welding List" is issued by the "Welding Engineer" to plan welding activities. As minimum, it is identified for each weld:

- weld number
- applicable drawing
- welding material
- base material
- PQR [Exhibit 10.16](#)
- WPS [Exhibit 10.18](#)

10.1.2. Based on this information, "Welding Engineer" decides whether new PQR are necessary. "Welding Engineer" is responsible for setting up and implementing the welding procedure qualifications ([Exhibit 10.23](#)) and arranges for heat treatment, machining and testing of weld test coupons. PQR are qualified and comply with contractual requirements.

"Welding Engineer" from CTA shall witness the welding of the weld test coupon and record the welding parameters used on the Welding Record (WR, [Exhibit 10.01](#)) for welding qualifications. In case the presence of a third party is requested, it shall be taken into account by "Welding Engineer".

After satisfactory evaluation of test results, "Welding Engineer" prepares the PQR recording the welding data and test results. PQRs are then reviewed and approved by a different person belonging to "Welding Development" unit and certified by the person in charge of "Welding Development" unit, in accordance with [GP.05.17](#). PQR are filed by "Welding Engineer" and available to all Ensa departments for use as needed.

10.1.3. WPS list the essential, supplementary essential and non-essential variables for the welding process and are supported by already qualified PQRs. WPS and changes thereto are prepared by "Welding Development" in accordance with procedure [GP.05.17](#). WPS are distributed according to [Section 07](#) of this Manual.

10.2. WELDER AND WELDING OPERATOR PERFORMANCE QUALIFICATION

10.2.1 "Welding and Heat Treatment manager" from "Production" establishes and implements the training program for welders and welding operators. After training, each welder or welding operator is subjected to a performance qualification tests in accordance with contractual requirements.

The welding procedures used to qualify welders and welding operators include all performance essential variables.



WELDING

SECTION **10**

“Welding Foreman” shall witness the welding of the weld test coupon and record the welding parameters used on the Welding Record (WR, [Exhibit 10.11](#)).

“Welding Development manager” is responsible for the administration, evaluation and certification of the welder qualification tests [Exhibit 10.19](#). Qualification data are then electronically entered in a welder qualification file by “Welding technicians”.

10.2.2. Welders Identification Numbers

A number to identify a qualified welder with all welding activities will be taken from his Staff number. In the event of the welder leaving the Company, the number is permanently removed.

This number will be recorded in:

- Welder qualification record and
- all Welding Records related with all welding operations carried out by the qualified welder or welding operator to ensure traceability. No stamps are issued.

10.2.3 The data of the welding activities are used to update welder’s qualification file when performing a weld to keep the qualification he holds according the Code requirements and updates the data base of “Qualified Welders List” . “Qualified Welders List” must contain the minimum following information:

- welder qualification identification number
- welder name
- welder qualification group
- expiration date

“Qualified Welders List” includes a warning for a qualification approaching expiration by entering a “C” next to the expiration date. “Qualified Welders List” is updated every time a change occurs by “Welding technicians” in the on–line system. “Qualified Welders List” is also used by “Welding Foremen” to control welders and welding operators’ qualification status. “Welding Foreman” may make appropriate job assignments to allow all welders to maintain the qualifications they hold.

10.2.4 The performance qualifications of welder or welding operator shall be affected depending on construction code requirements.

All other qualifications not questioned remain in effect.

10.3. RECEIVING INSPECTION AND ACCEPTANCE

[GP.10.01](#) "Reception of Welding Material" describes in detail the receiving inspection activities. “Warehouse operator” upon receipt of material checks and inspects material for identification and marking in accordance with material specification. He checks for damage, places the material in the Store and tags each lot or batch with yellow control label (see base and welding materials Control Labels, [Exhibit 10.05](#)) and fills in a MR.

QAS checks the MR, PO and CMTR and fills in the applicable portion of the SR and transmits it, via Intranet, to “Welding technicians”. The Vendor’s CMTR is verified by QAS for conformance to the applicable welding material procurement specification.



WELDING

SECTION **10**

Welding materials are tested when requested as specified in the SR. Testing is performed either by the Material Organization, Ensa or both. Samples of welding material to be tested are collected by "Welding Engineer", when required.

In case of rejection or scrapped, a red label ([Exhibit 08.10](#)) is stickered by "Warehouse operator" in accordance with [Section 15](#) for handling Non Conformance material.

10.4. STORAGE, CONDITIONING AND TRACEABILITY

All welding material is stored in accordance with [GP.10.08](#). "Logistic Technicians" is responsible for the "Welding Material Store".

"Welding Material Store" shall be clean and dry and separated from the other storage areas (see [Exhibit 10.22](#)). The measures taken for moisture control, baking and re-baking of electrodes, are detailed in [GP.10.08](#). When containers are open, coated electrodes and fluxes, are kept in ovens at temperatures, or reconditioned as specified below.

Traceability of welding material shall be maintained through identification of contract, receiving date, heat and lot, is maintained during storage by labelling containers or spools. The wire is stored in their original container while in storage.

It is allowed to transfer wire from a coil to a bigger or smaller type of coil according to production needs. Identification of contract, receiving date, heat and lot is maintained. It is not allowed to mix different lots in the same coil.

10.5 ASSIGNMENT OF WELDING MATERIAL

"Methods Engineer" has included the sequence, material type, diameter and quantity estimated of welding material for each welding operation of the IPP. With this information, "Welding technicians" through "MA Producción" application and taken in consideration the welding process specification, defines the material quality, heat/lot, diameter, material designation to be assigned to each IPP operation.

QC and "Welding Foreman" can verify that the material required in the WPS is the one required in the WPS.

"Warehouse operator" requests welding material from the "Welding Material Store" to the "Welding Material Storeroom" (Pañol) depending upon the production needs. Electrode ovens are in a locked area. Each oven is identified as described in [GP.10.08](#) and electrode material movements are registered in the application "MA Pañol". Electrodes belonging to different lots are placed on separated trays.

10.6. ASSIGNMENT OF WELDERS TO WORK

"Welding Foreman" assigns the work to be done by selecting the process between the different possibilities defined to be used between the different possibilities defined in the IPP and the welder/welding operator from the "Qualified Welders List". "Welding Foreman" assigns only welders qualified in accordance with the code number given in the applicable WPS identify in the welding operation of the IPP.

10.7 WELDING MATERIAL DISTRIBUTION



WELDING

SECTION **10**

Issuance of weld material to the assigned welder / operator is controlled through use of "MA Pañol" application. When the welder asks for the release of material, "Welding Material Warehouse operator" (Pañolero) verifies the assignation of the welder to an IPP operation and the material assigned.

The traceability of distributed material is maintained by identification the heat/lot, diameter and quality either by metal tags in the portable electric heated quiver for electrodes and containers for rods or labels on spools for wire. Fluxes are deposited in holding ovens provided under responsibility of "Welding Foreman" with clear identity to the lot and quality [Exhibit 10.13](#).

The welders receive only one type of electrode per portable quivers.

Prior to commencing welding, filler material identification by diameter, heat/lot and SR is entered on the Welding Record (WR) the "Welding Foreman".

In case a welder returns to the "Welding Material Storeroom" an amount of material either because of the task has been finished, at the end of each shift or because a change in working post, "storekeeper" will introduce the quantity back in the application "MA Pañol".

Wire and Rods

Spools of wire are maintained on the machine or returned to the "Welding Material Storeroom" when welding is completed. The material shall be identified in the same manner as when originally issued and if not identified it shall be scrapped or used in training welders/operators.

Electrodes

If the welder has to change jobs, the remaining electrodes together with the portable quiver, are returned to the "Welding Material Storeroom". The returned electrodes are examined by "Welding Material Warehouse operator" and are handled as follows:

- a) All electrodes that are in good condition are returned to stock in the corresponding oven.
- b) Damaged electrodes are scrapped.
- c) Any questionable electrodes are scrapped or used in training welders.

10.8. WELDING MONITORING

Control through monitoring of welding and heat treatment activities is performed by "Welding Foremen" and "Heat Treatment operators" according to the applicable documentation.

Each "Welding Foremen" and "Heat Treatment operator" involved in monitoring of welding and heat treatment operations shall be certified to perform the assigned inspection task in accordance with [Section 02](#) of this Manual.

Each monitoring activity of welding and heat treatment operations shall provide for recording objective evidence of monitoring results versus the acceptance criteria



WELDING

identified in the IPP/ HR, WPS, procedures or specifications.

The "Welding Foreman" and/or "Heat treatment operator" is responsible for the monitoring that preheat and/or interpass temperature is at required temperature during welding and records it as indicated in [GP.10.05](#). They shall be responsible for assuring the necessary postheating (soaking) of the piece is performed previously decrease the temperature below the minimum preheat temperature indicated in the WPS, if requested.

If at any time the temperature is found to be out of the required range, this is immediately reported to QC and handled in accordance with [Section 15](#) and/or 16 of this Manual.

10.9. WELDING RECORD

For pressure retaining welds attachments to pressure retaining materials or safety related items, the Welding Record (WR) (see [Exhibit 10.11](#)) is used to record welders , welding materials, WPS and to monitor that welding parameters used during the process, preheat and interpass temperature are correct, soaking activities.... The WR assures the required traceability as to welders and welding material employed against each welded joint.

For non pressure retaining joints, and/or non safety related welds a welding certificate ([Exhibit 10.15](#)) may be used to summarize welding information of a group of welds.

For tube to tube-sheet welds, WR could be selected from the [Exhibit 10.03](#), [10.09](#) and [10.12](#) according with project requirements.

The welding information is filled in accordance with [GP.10.05](#). After completion of the weld, "Welding Foreman" delivers the WR to QC which after review, it will be sent to "Data Book".



WELDING

SECTION **10**

REFERENCES

Exhibit 10.01	Laboratory Welding Report
Exhibit 10.02	Welding record for automatic processes
Exhibit 10.03	Tube to tube sheet WR
Exhibit 10.05	Base and Welding Materials Control Labels
Exhibit 10.08	Hydraulic expansion certificate
Exhibit 10.09	Welding record tube to tubesheet (type 2)
Exhibit 10.11	Welding Record format for retaining pressure parts/safety related parts
Exhibit 10.12	Tube to tube sheet welding record (type 1)
Exhibit 10.13	Ovens material movement sheet
Exhibit 10.15	Welding record
Exhibit 10.20	Filler Material Test Register
Exhibit 10.22	Weekly Temperature and Humidity control
Exhibit 10.23	Preliminary welding procedure specification



HEAT TREATMENT CONTROL

SECTION **11**

11.0 PURPOSE

11.1 HEAT TREATMENT SPECIFICATIONS

11.2 HEAT TREATMENT

REFERENCES



HEAT TREATMENT CONTROL

SECTION **11**

11.0 PURPOSE

To describe the system established to assure that heat treatments are controlled in accordance with the rules of the applicable Code and/or contractual requirements and are accomplished by qualified personnel using qualified written specifications, prepared and approved.

11.1 HEAT TREATMENT SPECIFICATIONS

11.1.1. Heat treatment requirements are included on specifications and referenced on the IPP. Selection, preparation, review and approval of heat treatment specification are as per in accordance with [Section 05](#) and [06](#). Review from a qualified heat treatment Level III operator is required.

In case of specific applicable requirements about the furnace, temperature control or temperature measurement, they shall be taken into account in the applicable specification or in the installation maintenance.

Distribution of heat treatment specifications will be as per [Section 07](#). The above-mentioned documents cover the intermediate and final heat treatments.

11.2 HEAT TREATMENT

11.1.2. Heat treatment shall be performed in controlled furnaces and temperature surveyed with calibrated thermocouples, in contact with the material or attached to blocks in contact with the material, and registers as per [Section 14](#).

Natural gas furnace is verified every 2 years or following a repair or modification by using an internal procedure by locating thermocouples in different zones to determine the heating characteristics.

For post-weld heat treatments performed with local installations, it will be verified before execution ([Exhibit 11.04](#))

11.2.2. Furnace operator, after completion of each heat treatment, collects the time-temperature charts, identify Contract no., Item no., IPP no., Specification no. and revision, Furnace no., identification and placement of thermocouples attached to the material, date of heat treatment and identification of operator. Such data will be forwarded to the "Heat treatment Level III".

"Heat treatment Level III" ensures that heat treatment is performed to the approved specification as referenced in the IPP.

11.2.3. "Heat treatment Level III" checks the time temperature charts, signs, dates and transmits them to QC for review of the heat treatment certificate (see [Exhibit 11.01](#), [Exhibit 11.03](#)) to be afterwards sent to "Data Book". When necessary, a summary of the accumulated heat treatment time will be documented through [Exhibit 11.02](#).

Heat treatment certificate shall record, as minimum:

- Item heat treated
- Date of heat treatment
- Heat treatment specification



HEAT TREATMENT CONTROL

SECTION **11**

- Furnace and thermocouples identification
- Holding time and temperature
- Heating and cooling rate
- Result of the treatment
- Quality Controller review person

11.2.4. Time-temperature chart and the heat treatment certificate constitute the official Quality Records and are filed at "Data Book" to assure conformance to the applicable specification. Copies of the records are made available to TPI or NB and Customer Inspector.

Time-temperature chart are not included in the Data Report.

REFERENCES

- [Exhibit 11.01](#) Single Heat treatment Certificate.
- [Exhibit 11.02](#) Summary Heat Treatment Certificate
- [Exhibit 11.03](#) Single Heat Treatment Certificate
- [Exhibit 11.04](#) Local PWHT furnace inspection record



NON DESTRUCTIVE EXAMINATION

SECTION **12**

12.0 PURPOSE

12.1 TRAINING, QUALIFICATION AND CERTIFICATION OF NDE PERSONNEL

12.2 NON DESTRUCTIVE EXAMINATION SPECIFICATIONS

12.3 DOCUMENTATION

REFERENCES



NON DESTRUCTIVE EXAMINATION

SECTION 12

12.0. PURPOSE

To describe the system established to assure that non destructive examinations are controlled in accordance with the rules of the Code and/or contractual requirements and are accomplished by certified personnel using qualified specifications.

12.1. TRAINING, QUALIFICATION AND CERTIFICATION OF NDE PERSONNEL

12.1.1 All qualifications are in accordance with contractual requirements.

12.1.2 -Reserved-.

12.1.3 -Reserved-.

12.1.4 Subcontracted NDE activities shall be performed by organizations surveyed and audited in accordance with provisions of [Section 08](#) of this Manual.

12.1.5 [Reserved].

12.2. NON DESTRUCTIVE EXAMINATION SPECIFICATIONS

12.2.1 In addition to the selection, preparation, review and approval of NDE specifications required by [Sections 05](#) and [06](#) of this Manual, approval from a qualified "NDE Level III " is required.

All non-destructive examinations are performed in accordance with distributed documentation as per [Section 07](#) and in accordance with the process control defined in [Section 09](#) of this Manual.

12.2.2 NDE specifications may be qualified by actual demonstration which is documented when applicable on a Specification Qualification Record (SQR) [Exhibit 12.13](#).. NDE specifications are qualified as follows:

- a) Radiographic examination (RT) is performed in accordance with written specifications which show methods, techniques and parameters to be employed during the examination. The sensitivity of the examination is proved by means of the penetrameter image in the radiography and satisfactory density.
- b) Ultrasonic examination (UT) is performed in accordance to written specification, specifying the techniques to be utilized. Qualification is evidenced by repeatable indication from an artificial defect in a calibration block. Any change in an essential variable required by the method shall require a requalification.
- c) Magnetic Particle (MT), Liquid Penetrant (PT) and Visual Examination (VT) are conducted within the parameters of a written specification. Repeatable results from a known defective specimen are evidence of the technique qualification.

12.2.3 -Reserved-.

12.3. DOCUMENTATION

Ensa non-destructive examinations will be registered in records according with:

-VT [Exhibit 12.01](#)



NON DESTRUCTIVE EXAMINATION

SECTION **12**

- PT [Exhibit 12.02](#)
- MT [Exhibit 12.03](#)
- RT [Exhibit 12.04](#)
- UT [Exhibit 12.05](#)
- LT [Exhibit 12.08](#)

REFERENCES

- [Exhibit 12.01](#) Miscellaneous Controls (CV)
- [Exhibit 12.02](#) Liquid Penetrant Certificate (PT)
- [Exhibit 12.03](#) Magnetic Particles Certificate(MT)
- [Exhibit 12.04](#) Radiographic Certificate(RT)
- [Exhibit 12.05](#) Ultrasonic Certificate(UT)
- [Exhibit 12.08](#) Leak Testing Certificate(LT)
- [Exhibit 12.09](#) NDT personnel qualification certification
- [Exhibit 12.10](#) Education, experience and training data sheet
- [Exhibit 12.12](#) Technical evaluation record.
- [Exhibit 12.13](#) Specification Qualification Record (SQR)



HANDLING, STORAGE, SHIPPING AND PRESERVATION

SECTION **13**

13.0 PURPOSE

13.1 MATERIAL HANDLING

13.2 STORAGE AND PRESERVATION

13.3 CLEANING, PACKAGING AND SHIPPING

13.4 SPECIAL HANDLING, STORAGE, PRESERVATION, CLEANING,
PACKAGING AND SHIPPING

13.5 MANTAINANCE

REFERENCES



13.0. PURPOSE

To describe the measures established to control handling, storage, shipping, cleaning, packaging and preservation of items in accordance with established specifications, procedures or drawings, to prevent damage, deterioration or loss.

13.1. MATERIAL HANDLING

13.1.1 Personnel

"Crane operators" are subjected to annual visual medical checks and are qualified according to [GP.02.09](#). All materials handling personnel are under the direct supervision of the "Assembly Foremen". All materials handling personnel receive initial training prior to assignment.

13.1.2 Lifting Lugs and Handling Device

Temporary lifting lugs are installed as shown in the fabrication drawings prepared by "Tooling Engineer" in accordance with reference Code or contractual requirements and specified in the IPP/HR, when they are welded directly to the pressure retaining part. Permanent lifting lugs are normally specified by contract. If these lugs are to be employed during fabrication in such a manner that they may sustain damage, temporary protective measures shall be taken. Cradles, positioning rings and equipment, skids, and other handling devices are employed to minimize and simplify the required movements.

Special handling devices are defined and constructed according to drawings prepared by "Tooling Engineer".

13.1.3 Procedures

Procedures on the safe practices, sketches and specified handling methods on major operations are included in the applicable documentation and distributed to the shop. In addition, handling drawings issued by "Tooling Engineer" containing specified details for specific operations are used.

Preparation of procedures by "Documentation Engineer" shall take into consideration Customer requirements as defined in their specification.

13.1.4 Inspection of Lifting Equipment

All the lifting equipment will comply with the national safety regulations. The guide lines for inspection of chain slings, wire rope slings, shackles, eye bolts, plate clamps, hoisting ropes, crane hooks and the remaining lifting equipment used are included in [GP.13.01](#).

In addition to visual examination, all hooks are periodically non-destructively tested. The person in charge of the "Health and Safety" is responsible for implementation of the inspection program.

13.2. STORAGE AND PRESERVATION

13.2.1 "Logistic technician" is responsible for storage of items. Materials storage and conditioning is controlled by written procedures prepared and independently reviewed and approved by "Documentation Engineer". When no specific procedures are issued, [GP.13.05](#) must be followed. This control includes raw materials, subassemblies and



HANDLING, STORAGE, SHIPPING AND PRESERVATION

SECTION **13**

manufactured products.

13.2.2 For particular items, when necessary, the requirements of special environmental protections, such as inert gas atmosphere, control of moisture content and temperature levels, are specified in Ensa specifications, provided and verified on a special record for the item.

13.2.3 Welding material storage is managed as per [Section 10](#) of this QM.

13.3. CLEANING, PACKAGING AND SHIPPING

13.3.1 Written procedures are established by "Documentation Engineer" for cleaning and packaging including marking and labeling for shipping of each nuclear component, subassembly, etc. These procedures must comply with the corresponding contract requirements. QC is responsible for verifying on the IPP/HR the implementation of these procedures.

13.3.2 Shipping process is defined in [GP.13.02](#) . For finished products, IP will prepare Packing List [Exhibit 13.03](#) to identify the items to be sent and "Warehouse operator" the Delivery Note [Exhibit 13.05](#).

None finished products is delivered from Ensa shops until the Shipping Release (See [Exhibit 13.01](#)) is completed and properly signed by QAM and QAE .

13.4. SPECIAL HANDLING, STORAGE, PRESERVATION, CLEANING, PACKAGING SHIPPING

For such special activities, a procedure shall be developed in accordance with [Section 05](#) of this Manual and it shall be the responsibility of QC to verify the implementation of such procedures through the IPP / HR operations.

13.5. MANTEINANCE

Maintenance operations are under "Maintenance operators" responsibility and defined in [GP.13.06](#). A maintenance plan is performed and recorded through [Exhibit 13.07](#) and [Exhibit 13.08](#).

REFERENCES

- [Exhibit 13.01](#) Shipping Release (AE)
- [Exhibit 13.02](#) Shipping Authorization
- [Exhibit 13.03](#) Packing List (PL)
- [Exhibit 13.04](#) Temporary Exit Authorization
- [Exhibit 13.05](#) Delivery note
- [Exhibit 13.06](#) Certificate of Compliance
- [Exhibit 13.07](#) Preventive maintenance
- [Exhibit 13.08](#) Self-maintenance
- [Exhibit 14.06](#) Maintenance of ovens



CONTROL OF MEASURING AND TEST EQUIPMENT

SECTION **14**

14.0 PURPOSE

14.1 RESPONSIBILITIES

14.2 CALIBRATION

14.3 CALIBRATION PROCEDURES

14.4 DISCREPANT MEASURING OR TESTING EQUIPMENT

14.5 CALIBRATION RECORDS

REFERENCES

CONTROL OF MEASURING AND TEST EQUIPMENT

SECTION 14

14.0. PURPOSE

To establish a system which assures that tools, gages, instruments and other measuring and testing equipment and devices used in activities affecting quality are of the proper range, type and accuracy to verify conformance to established requirements and are calibrated and properly adjusted at specified periods or use intervals to maintain accuracy within necessary limits as defined in [GP.14.01](#).

Calibration process under ISO-17025 accredited system is managed within its system.

14.1. RESPONSIBILITIES

14.1.1 The **person in charge of "Metrology"**, belonging to CTA has the following duties:

1. Establishing the calibrated equipment to be used for production and certifying activities. The list of calibrated equipment is available through the on line system.
2. Marking of equipment, each piece of equipment shall have a unique permanent identification.
3. Calibration of all measurement, test and examination equipment used, identifying and reporting those out of calibration.
4. Training, indoctrination and qualification of "Metrology" personnel, (see [GP.02.09](#)).
5. Filing calibration records.

14.1.2 **Personnel using calibrated equipment** are responsible for:

1. Sending or making available to "Metrology" unit affected equipment to be calibrated when requested.
2. Using the equipment within the specified calibration period and for reporting to QC any suspected inaccuracies of the equipment.
3. Selecting the proper calibrated equipment to perform the required work inside the applicable tolerances.
4. Manage and storage the equipment in a safe condition to avoid its damage or deterioration.

14.2. CALIBRATION

14.2.1 All calibrated equipment is labeled by "Metrology technician" (see [Exhibit 14.01](#) and [14.02](#)), indicating current calibration status. If identification is missing, it is assumed that the equipment is out of calibration until the equipment can be identified and the calibration verified.

In case of limitation, it shall be recorded through [Exhibit 14.07](#).

Traceability between equipment and the items on which it is used, is by means of documenting the equipment Serial Number on the Inspection Records, covering the examination or manufacturing operation. The inspection records are identified on the relevant operation of the applicable IPP / HR.

14.2.2 Equipment is used only within the specified calibration period. No equipment is used for the fulfillment of requirements unless it is included on the list of calibrated equipment.



CONTROL OF MEASURING AND TEST EQUIPMENT

SECTION **14**

14.2.3 Calibration frequency is described in [GP.14.01](#). Calibration intervals shall meet applicable Code and contractual requirements, when these are specified.

14.3. CALIBRATION PROCEDURES

Calibration methods and acceptance criteria are described in written procedures included in the Laboratory procedures. Calibration shall be against measurement standards which have known relationship to national standards, where such standards exist. When such standards don't exist, the equipment manufacturers' standard shall be used and documented.

Reference standards shall have a minimum accuracy 4 times greater than that of the measuring and test equipment being calibrated to ensure that the reference standards contribute no more than 1/4 of the allowable calibration tolerances. Where the 4 to 1 ratio can not be maintained, the basis for selection of the standard shall be technically justified.

14.4. DISCREPANT MEASURING OR TESTING EQUIPMENT

When discrepancies in measuring or testing equipment are found at calibration, "Metrology manager" issues an action in the CAPA system indicating in the field "Origin" as "Instrument out of tolerance" and the field "Classification" as "CAR" which is sent to the QAM.

Proprietary of the instrument shall review the products manufactured while using the discrepant equipment and shall determine the effect the inaccuracy may have had on the completed product and shall evaluate the effect of this out of tolerance on the material and recording the result of the evaluation on the CAR.

If any nonconformity is found during re-examination, a Non Conformance Report shall be generated and treated as per [Section 15](#) of this Manual.

14.5. CALIBRATION RECORDS

Calibration Certificate to be maintained for each piece of equipment or set which includes the following data:

- Equipment description
- Serial number
- Range
- Procedure number and revision
- Serial number of master gage used for calibration
- Date
- As found (when instrument as found out of tolerance) and as left conditions
- Name of individual performing calibration

Calibration procedures and certificates of calibration shall be maintained by "Metrology manager".



CONTROL OF MEASURING AND TEST EQUIPMENT

SECTION **14**

REFERENCES

- [Exhibit 14.01](#) Calibration labels
- [Exhibit 14.02](#) Out of tolerance and pending of calibration labels
- [Exhibit 14.07](#) Limitation of Use



NON CONFORMING ITEMS

SECTION **15**

15.0 PURPOSE

15.1 IDENTIFICATION OF NON CONFORMITIES

15.2 SEGREGATION OF NON CONFORMITIES

15.3 DISPOSITION OF NON CONFORMITIES

15.4 DOCUMENTATION OF NON CONFORMITIES

15.5. DEFICIENCIES RELATED WITH REGULATORY REQUIREMENTS

REFERENCES



NON CONFORMING ITEMS

SECTION 15

15.0. PURPOSE

This section describes the measures established to control items or activities which do not conform to specified requirements in order to prevent their inadvertent use, by providing procedures for identification, segregation, disposition and documentation.

15.1. IDENTIFICATION OF NON CONFORMITIES

[GP.15.01](#) details the system used for handling of non conformities (NCR). NCR shall be issued and managed through the NCR application which is available to Ensa personnel, Customer and TPI, NB through the online system. Access to the NCR application is granted through username and password which are unique for each individual.

QC, QAE or QAS who either detects or is informed of the nonconformity generates a NCR (see [Exhibit 15.01.](#)) completing the description with all required information. NCR number is generated by the on-line system in an automatic and consecutive manner per component.

QC enters the word "No Aceptable" or "No Conforme", his name and date in the applicable column of the corresponding IPP operation through application "Control de Procesos" by logging their username and password. The NCR number is shown in the applicable operation. For NCRs identified in receiving inspection, the number is identified in the IR/SR.

For non conformances identified in the shop, "Production Project Manager" shall include the cause. In case that NCR is identified at the Ensa suppliers/subcontractors, the causes must be provided by the originator of the NCR.

When a rework process is included in the IPP, it does not require the issuance of a NCR or additional information. These conditions are detected by planned controls or NDE examinations and it is documented by QC in the initial NDE operation or quality control certificate making reference to the rework operations which are included on the IPP for restoring the specified conditions. (see [GP.15.01](#))

15.2. SEGREGATION OF NON CONFORMITIES

All nonconforming items, as soon as detected in Ensa shop, are tagged by QC and shall decide if the yellow Hold Tag or the green Hold Tag is to be used according to [GP.15.01](#) (see [Exhibit 15.02](#)). The green tag indicates that no further work may continue on the part of the item in which the deficiency has been reported. The yellow tag indicates that no work may continue on the total item.

There are situations where tagging may not possible or it may not be seen because of the geometry, size, etc.: the application "Control de Procesos" displays a column "NCR" which shows the NCR number issued for that operation and their status.

Tags shall be removed by QC once the NCR have been closed.

If the disposition is "reject" or "return to the supplier", QC removes the "Hold Tag" from the item and replaces it with the red "SCRAP MATERIAL NOT USABLE" tag (see [Exhibit](#)



NON CONFORMING ITEMS

[15.02](#)). QC shall instruct "Production" to remove the item from the manufacturing area and segregate it in a hold area, whenever possible.

15.3. DISPOSITION OF NON CONFORMITIES

15.3.1. The NCR is sent to IP for assignment of disposition through NCR application in the online system. The IP shall decide whether the NCR must be submitted to the customer for approval, to "Method Engineer" or "Design and Analysis Engineer" for design reconciliation. The notification system for each stage of NCR resolution shall be by e-mail.

Dispositions are:

- Use-as-is: after reconciling design output documents with the item's as-built condition and verifying that applicable requirements are met.
- Repair: physically restoration of the condition that conform requirements.
- Scrap: Rejection of the item.

15.3.2. QAE shall include corrective actions if applicable, selection of submittal for approval to NB, TPI ,when required, and decide if the NCR is subject to 10CFR21. When applicable, the TPI, NB concurrence shall be included in the NCR by TPI, NB or QAE through the NCR application in the online system as described in [GP.15.01](#).

TPI, NB concurrence may be attached in the NCR by QAE after reception of written evidence stating the TPI, NB concurrence.

The corrective/preventive actions requested in the NCR are issued through the CAPA system and are managed according to [Section 16](#). In case of particular corrective/preventive action is requested, it can be identified directly in the NCR. Verification of it implementation is responsibility of the QAE.

Actions to contain the effect of the non-conformity on other processes or products or suspension of provision of product and services, contingency actions, must be considered.

15.3.3. In establishing the disposition of a NCR, the IP shall consult with any other organization that may contribute to the decision. More detailed information on those performing evaluation of Non Conformities in [GP.15.01](#). He shall consult the Manager of any other unit that may contribute to the resolution.

15.3.4. Once "Methods Engineer", "Design and Analysis Engineer" and QAE have completed their corresponding evaluation when requested, IP shall approve the final disposition and technical justification of the NCR.

The NCR shall be submitted to the Customer when contractually required. The Customer disposition shall be included in the NCR by the Customer or IP (alternatively QAE or JP) through the NCR application in the online system as described in [GP.15.01](#).

Customer disposition can be entered in the NCR by IP after reception of transmittal, letter, fax, e-mail or written evidence stating the Customer disposition.



NON CONFORMING ITEMS

SECTION **15**

After disposition of the NCR by IP and concurrence of Customer, TPI or NB as applicable, the IP (alternatively QAE or JP) shall proceed with the distribution of the NCR as described in [GP.15.01](#) and release the item for further work in accordance with NCR disposition.

15.3.5. When necessary, manufacturing and inspection operations to be performed for the resolution of the NCR, including base metal repairs, shall be described in the NCR or in IPP (see Section 9 of this Manual) which will be referenced in the NCR.

15.3.6. When a NCR is identified at the receiving inspection, two cases may arise:

- a) The material does not require being repaired/reworked.
- b) The material requires repair/rework in Ensa shop.

In the first case, QAS will not issue the IR/SR, holding the material until the NCR is solved.

In the second case the IR/SR is accepted pending the repair established in the NCR. The NCR is reflected in the IR/SR. The NCR is distributed to the shop and entered in the IPP in the receiving inspection operation. The NCR is handled as described in this section.

15.3.7 The closure of the NCRs shall be performed through the online system by QA personnel who verifies that the disposition has been accomplished as described in [GP.15.01](#).

15.4. DOCUMENTATION OF NON CONFORMITIES

Documents related with the NCR identified will be made available to "Data Book" through the application Ensa CDP, PLM or "Control de Procesos".

15.5. DEFICIENCIES RELATED WITH REGULATORY REQUIREMENTS

When applicable, defects detected on parts, products or services under US legal regulation 10CFR21, it shall be manage in accordance with [GP.15.05](#) "Reporting of defects and non-compliance under 10 CFR 21".

When applicable, defects detected on parts, products or services under other countries legal regulation, it shall be managed in accordance with regulatory and contractual requirements.

REFERENCES

- [Exhibit 15.01](#) Non Conformance Report (NCR)
- [Exhibit 15.02](#) Non Conforming Material Labels
- [Exhibit 15.06](#) Anomalies during Clean Area Activities



CORRECTIVE ACTION

SECTION **16**

16.0 PURPOSE

16.1 IDENTIFICATION AND DOCUMENTATION OF CONDITIONS
ADVERSE TO QUALITY

16.2. DISTRIBUTION AND CONTROL OF CAR

REFERENCES



CORRECTIVE ACTION

SECTION **16**

16.0. PURPOSE

To describe the system established to assure that conditions adverse to quality related (CAQ) with failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances cause are determined and corrected to preclude repetition.

NCR related with the product and/or services shall be managed in accordance with [Section 15](#).

16.1. CORRECTIVE AND PREVENTIVE ACTIONS

16.1.1. The process for the issuance and approval of Corrective Action Reports (CAR [Exhibit 16.01](#)) in CAPA system is described in [GP.16.01](#).

There are several situations to be managed with these kinds of actions, for example:

- to avoid the repetition of deviation managed with NCR.
- actions identify during a Root Cause Analysis (RCA) [Exhibit 16.05](#) and [Exhibit 16.06](#)
- Recurrence and/or negative trends in the performance of the quality system.
- a detection of a potential quality problem of significant magnitude is indicated on the basis of safety, cost, or failure possibility in design or fabrication activities at Ensa or by Vendors.
- audits to Vendors in accordance with [Section 08](#).
- internal audits in accordance with [Section 17](#) and [GP.17.01](#).

16.1.2. Other units are permitted to submit requests to QA for the issuance of a CAR for the resolution of a problem affecting the quality or process of the product. These requests are to be made in writing, explaining the problem or nonconformity, including the applicable documentation and addressed to the QAM.

16.1.3 Issuer responsibilities include the description of the complete scope of the problem, cause and the definition of the appropriate corrective actions in agreement with the responsible of the action.

The issuer of the CAR shall initiate an investigation to determine the cause of the condition with support from the any of the different areas and shall indicate the action to be taken to correct the identified condition and prevent recurrence when applicable. In case necessary, a Root Cause Analysis will be performed in accordance with [GP.16.02](#). The person responsible for the action as well as the closing date foreseen will also be included.

16.1.4 The access to the CAPA system it will be necessary to have a confidential user's password. "Digital transformation and Information Systems" is responsible for the filing of the CARs registered through the CAPA application.

16.2. DISTRIBUTION AND CONTROL OF CAR

16.2.1. CAR is registered in the CAPA system. CAR is distributed to the people in charge of establishing the corrective action and his superiors, "Senior Vice-President Managing Director" and any other personnel deemed necessary by the issuer.



CORRECTIVE ACTION

SECTION **16**

The CAPA system shall advise, after approval of the CAR, its issuance and actions to be taken by the person mentioned in the actions. In case of exceeding the time foreseen date and the action is not taken by the person responsible for it, the CAR issuer shall notify such issue to the QAM for resolution.

16.2.2. Once all the actions in the CAR are completed and verified by the issuer, they must also verify the effectiveness of the CAR to assess the adequacy of the actions taken by evaluating the recurrence of similar subjects, trends, performance, etc... In order to consider an appropriate period of time to perform such evaluation, the effectiveness of the proposed actions shall be performed minimum three months after all the actions of the CAR are completed.

In the event that the verification of the effectiveness is found not satisfactory, it shall be issued a new CAR to address the actions deemed necessary to resolve the condition adverse to quality reported.

16.2.3. Copies of the CAR shall be available to the NB, TPI, Regulatory Body or Customer.

REFERENCES

- [Exhibit 16.01](#) Corrective and Preventive Action Report (CAR)
- [Exhibit 16.05](#) Análisis de causa raíz / Root cause analysis (L1)
- [Exhibit 16.06](#) Análisis de causa raíz /Root cause analysis (L2)



AUDITS

SECTION **17**

- 17.0 PURPOSE
 - 17.1 RESPONSIBILITIES
 - 17.2 AUDIT SCHEDULE
 - 17.3 AUDIT TEAM REQUIREMENTS
 - 17.4 AUDIT PLAN
 - 17.5 AUDIT CHECK LIST
 - 17.6 AUDIT PERFORMANCE
 - 17.7 AUDIT REPORT
 - 17.8 FOLLOW UP
 - 17.9 RECORDS
 - 17.10 AUDITS TO QUALITY ASSURANCE
- REFERENCES



AUDITS

SECTION 17

17.0. PURPOSE

To establish a comprehensive system of planned and periodic audits to ensure compliance with all aspects of the Ensa Quality Program and to determine the effectiveness of the program.

17.1. RESPONSIBILITIES

- 17.1.1 The QAM is responsible for approving the internal audit program and resolving any lack of response or disputed items, with appropriate management.
- 17.1.2 The QAM is responsible for the overall scheduling and implementation of the Ensa internal audit program. QAM selects the audit team, appointing the Team Leader and approving the audit report, except as specified in para. 17.10.
- 17.1.3 "System Evaluation and Control Engineer" is responsible for issuing the audit schedule, assuring that audits are conducted as established in the audit schedule, follow up on open action items and re-audit as necessary.
- 17.1.4 The Management of the audited organization is responsible for the cooperation and assistance to the audit team during the audit performance, review of the results and taking of appropriate actions to assure correction of reported non-conformances and resolution of the auditors' comments.

17.2. AUDIT PROGRAM

An annual internal audit program is issued by "System Evaluation and Control Engineer". The schedule specifies the month of the year when functional Operating areas are to be audited and which Quality Program section is to be audited.

The audits are scheduled to assure that the entire Quality Program is audited at least once annually.

17.3. AUDIT TEAM REQUIREMENTS

QAM selects of the people to take part in the audit teams on terms of experience and training. No member of the team selected will be assigned to audit any task under his/her responsibility. Team Leader must be trained, qualified and certified as Lead Auditor in accordance with [GP.02.01](#) and [Section 02](#) of this Manual.

17.4. AUDIT PLAN

The Lead Auditor shall develop and document an audit plan for each audit ([Exhibit 17.04](#)). This plan shall identify the audit scope, audit personnel, organizations to be notified to, applicable documents and schedule.

17.5. AUDIT CHECK LIST

The audit team prepares a written check list, identifying the area to be audited, including questions or points to be investigated during the audit with reference to the Quality and/or General Procedures Manuals paragraph. The check list is approved by the QAM.

17.6. AUDIT PERFORMANCE



AUDITS

SECTION **17**

At the discretion of the Lead Auditor, a pre-audit meeting may be performed with the team and the management of the area to be audited. Audits are performed by the audit team following the prepared check list and comments documented on the check list (see [GP.17.01](#) for further details). The check lists are not limited as to questions and may be extended as necessary. Upon completion of the audit a post audit meeting is held to address the audit findings and bring the attention about those areas requiring immediate action.

17.7. AUDIT REPORT

All audits are documented by a written audit report (see [Exhibit 17.01](#)) which is prepared and issued by the Lead Auditor.

The audit report shall be signed by the Lead Auditor and shall include the following information, as appropriate:

- a) Description of the audit scope and details of objective evidence.
- b) Identification of the auditors.
- c) Identification of persons contacted during audit activities.
- d) Summary of audit results, including a statement on the effectiveness of the Quality Program elements which were audited.
- e) List of each reported audit finding with the reference in the CAPA system.

Each report is distributed to the Management of the area or organization audited in accordance with [GP.17.01](#).

CAR will be issued by the Lead Auditor, or by an ENSA Lead Auditor in case the service of auditing is subcontracted, in accordance with [Section 16](#) and [GP.16.01](#) following:

- Reporting Area: Quality Assurance
- Origin: Internal audit
- Classification: according to the type of finding (Observation, Deficiency and Recommendation).
-

Audited units will carry out the actions assigned by the Team Leader through the CAPA system in the foreseen dates.

17.8. FOLLOW UP

Lead Auditor will track any open action items by reviewing the corrective actions in the CAPA system and performing a tracking of such actions to verify their implementation. If actions are not satisfactorily completed, the corrective action system as detailed in [Section 16](#) of this Manual shall be used.

17.9. RECORDS

Results of audits are filed by the Lead Auditor in the SIDOCO or PLM and made available to the Customer, Regulatory Organization, NB or their representative.

17.10. AUDITS TO QUALITY ASSURANCE

Annual audits of QA are arranged by the "VP Finance, System and Quality" area with Lead Auditors having no responsibility in the areas being audited. Audits are performed as described in para. 17.02 to 17.09 and "Senior VP & Managing Director" will be



AUDITS

SECTION **17**

responsible for the required activities.

REFERENCES

- [Exhibit 17.01](#) Internal Audit Report
- [Exhibit 17.04](#) Internal Audit Plan



QUALITY ASSURANCE RECORDS

SECTION **18**

18.0 PURPOSE

18.1 DESIGNATION OF RECORDS TO BE MAINTAINED

18.2 QUALITY RECORDS GENERATION AND ACCUMULATION

18.3 RETENTION OF QUALITY RECORDS

18.4 STORAGE AND ACCESS TO QUALITY RECORDS

18.5 AUTHENTICATION OF QUALITY RECORDS

REFERENCES



QUALITY ASSURANCE RECORDS

SECTION 18

18.0. PURPOSE

To establish a system for generating, filing, retaining and transmitting Quality Records.

18.1. DESIGNATION OF RECORDS TO BE MAINTAINED

As a minimum the records to be maintained shall be those described in paragraph 18.3, however the Owner or its designee shall be responsible for designating the records to be maintained.

18.1.1. The QAM shall be responsible for the accumulation and safeguarding of the required records. At job completion all lifetime records shall be forwarded to the Customer and receipt acknowledgement obtained.

18.1.2. Ensa shall be responsible for the accumulation and safeguarding of non-permanent records specified on para. 18.3.2 for the retention periods specified in the ASME Code, as minimum. In no case need non-permanent records be retained for longer than 10 years after completion of applicable Code Data Report.

18.2. QUALITY RECORDS GENERATION AND ACCUMULATION

18.2.1. Ensa personnel originating Quality Records are responsible for their correct compilation and for assuring their legibility and reproducibility. Quality Records are indexed and identifiable by subject and date originated. Validation of records is in accordance with paragraph 18.5.

18.2.2. Design and analysis documents are generated and distributed in accordance with Sections 05, 06 and 07 of this Manual and retained in the originators files.

18.2.3. PO are generated, filed and maintained by "Procurement Manager".

18.2.4. Vendors surveys, audits and vendors submittals such as procedures, IPP and CMTR are accumulated and maintained by QAS.

18.2.5. Quality Records generated at Ensa shop and during installation activities at Field Sites are listed on the IPP that is the basic tool for identification and accumulation of records. They are accumulated and maintained by QC and "Site Quality Inspector" respectively, until completion of the IPP and then available to "Data Book" for review and filing.

18.2.6. Personnel qualification records are maintained by the unit issuing the certification.

18.2.7. Calibration records are generated and maintained by "Metrology Manager" in accordance with Section 14 of this Manual.

18.2.8. Radiographs are maintained by QC and stored in special protected files located in bunker by the responsible of the bunker.

18.2.9. Code Data Reports are generated and maintained by QAM.

18.2.10. Internal audit reports are maintained by Lead Auditors in SIDOCO or PLM system.



QUALITY ASSURANCE RECORDS

SECTION **18**

18.2.11. [GP.18.01](#) gives details about Ensa system for accumulation, retention, protection, retrieval and disposition of Quality Records.

18.3. RETENTION OF QUALITY RECORDS

Quality Records are classified as "Lifetime" or "Non-permanent" in accordance with the following tables:

Lifetime Quality Records are the following:

- c) Index to lifetime records.
- d) Code Data Reports.
- e) Design Specifications.
- f) Design Output Documents.
- g) As built drawings.
- h) Certified Material Test Reports (CMTR), including listing of materials showing traceability to the location used.
- i) Heat Treatment records. (Heat treatment charts or certified summaries of time and temperature data).
- j) Final hydrostatic and pneumatic test results.
- k) Final nondestructive examination reports. Final radiographs as specified by the Owner for Section XI applications.
- l) Repair records when required.
- m) Weld Procedures.
- n) Overpressure Protection Report.
- o) Non Conformance Reports affecting those records listed from a) to k).
- p) NS-1 Certificate of Conformance.
- q) Training Records
- r) IPPs and Welding Records
- s) Documentation for nuclear facilities dismantling.

For Transport Containments according to Div. 3 the Quality records must cover the following instead of the mentioned d) and l):

- i. Fabrication Report
- ii. Construction Procedures
- iii. Drawings
- iv. Audits and survey reports.
- v. IPPs and Welding Records
- vi. Joint/Welders identification records.
- vii. Fabrication Specification.

Also, the following Non Permanent records will take part of the Permanent Records for Transport Containments according to Div. 3: f), i), j) and k).

Non-permanent Quality Records, are the following:

- a) Index to non permanent records
- b) Quality Program Manual (3 years after superseded or invalidated).
- c) Design, procurement and Quality procedures (3 years after superseded or invalidated).



QUALITY ASSURANCE RECORDS

SECTION **18**

- d) Installation and NDE procedures (10 years after superseded or invalidated).
- e) Personnel qualification records (3 years after superseded or invalidated).
- f) PO (10 years after superseded or invalidated).
- g) Audit and survey reports (3 years after completion of report).
- h) Final radiographs not covered in para. 18.03.01.i (10 years after completion).
- i) Calibration records (until recalibrated).
- j) CARs (3 years after completion of report)
- k) Certifying Engineer qualification records (3 years after superseded or invalidated).
- l) Records of temperature and relative humidity of welding material warehouse (1 year)

“Data Book” is responsible for binding and indexing the records.

18.4 STORAGE AND ACCESS TO RECORDS

18.4.1 The locations and facilities for storage of records whilst under Ensa’s control shall meet the prescribed standards for protection from deterioration and damage. Duplicate records may be stored in a separate remote location. (See detailed [GP.18.01.](#)). As an alternative to the physical storage, records may be electronically stored in the SIDOCO, PLM software or other application used. Access to the records (read only) shall be granted to all users of SIDOCO or PLM software with the exception of records related to certification of personnel. In this case, the access shall be restricted to personnel responsible for such certification or their designee. A back up copy of the records contained in SIDOCO, PLM software or other software used shall be performed on a daily basis and stored in a different location.

18.4.2 Access to physical storage of records is restricted to personnel belonging to QA. QAM is responsible for authorizing the access to personnel from other units. The records and the index thereto, are accessible to the Customer, Owner and NB.

18.4.3 A Log list [Exhibit 18.03](#) is used to control record removal from the QA filing facility.

18.4.4 When it is necessary to correct an error, it shall be accomplished by the originator of the record or other authorized personnel by a single line through the erroneous entry, entering the correct information and signing and dating the entry. Elimination of original entry by erasure or white-out shall not be permitted.

In order to facilitate the identification of the personnel who performs the correction, a log of the personnel per area or unit authorized to sign in quality records is maintained [Exhibit 18.02.](#) by the responsible of the area or unit.

18.5. AUTHENTICATION OF RECORDS

Documents shall be considered valid if signed off and dated by authorized personnel as per this Manual and applicable procedures. Similar to this, in the case of electronic documents, the authentication shall be performed by identification in the system of such documents and personnel who issued/reviewed/approved the documentation.

During compilation of records generated during contract development for elaboration of



QUALITY ASSURANCE RECORDS

SECTION **18**

Data Package to be delivered to Customer (when so requested), external signatures may be requested by external parties to evidence review of such Data Package. "Data Book" personnel shall print out copies of applicable records and gather external signatures for scanning and deliver.

REFERENCES

- [Exhibit 18.01](#) Records system
- [Exhibit 18.02](#) Signatures control
- [Exhibit 18.03](#) Authorized personnel to QA Vault Log list



FIELD OPERATIONS

SECTION **19**

- 19.1 GENERAL.
- 19.2 ORGANIZATION
- 19.3 RESPONSIBILITY



19.1. GENERAL

This section describes the system used by Ensa to extend the requirements of the Quality Program described in this Manual for field operations. An ASME Certificate of Authorization shall be required to extend activities to Field Projects subjected to an ASME audit of the site location.

All activities to be performed by "Services and Special projects" area shall be performed in accordance with the requirements of this Manual, except as modified herein.

The Site organization shall be established based on the scope/complexity of work and Site Quality Engineer reports to QAM. The field operations mentioned in this Section are those component completions, and/or installations to be performed on Code Items under the Corporate NPT and/or NA Certificates of Authorization.

An Addenda (Quality Plan) to this QM prepared by QAS or "Site Quality Engineer" or QAE shall detail for each site specific conditions such as organization and interfaces. This addenda may modify some requirements stated in this Section, but does not affect other sections relative to Ensa plant activities.

19.2. ORGANIZATION

For each site, a functional organization chart shall be included in the relevant site addenda to this QM.

19.3. RESPONSIBILITY

19.3.1. Quality Program

The overall responsibility for planning and implementation of the Quality Program is retained by the QM.

"Site Quality Inspector" is the responsible to perform and control all related activities of the Quality Program on those works performed by "Services and Special projects" area .

This Manual, Site Addenda and the General and Specific Procedures Manual as well as their revisions, shall be distributed to site by "Site Quality Inspector" under the same controlled conditions detailed in Section 1 of this Manual. These documents are available on sites to all affected Ensa's organization.

19.3.2. Indoctrination and Training

The requirements of Section 02 of this Manual shall apply for personnel assigned to field works. "Site Quality Inspector" is responsible of the control of the validity of the qualification of welders, NDE personnel and quality personnel during field operations.

19.3.3. Design Control

"Site Manager" shall receive and transmit to any involved party on-site the contract information as described in Section 05 of this Manual. This includes Work Order and its



changes with the related documentation, design documents, drawings and specifications.

"Site Manager" shall be responsible for informing the personnel under his responsibility about any field changes. "Services and Special projects" IP or "Documentation Engineer" to update the revision of affected documents. Alternatively, " Services and Special projects" IP may prepare the installation procedures following the same requirements established in this Manual 's [Sections 05](#) and [06](#).

"Documentation Engineer" or "Services and Special projects" IP shall generate documents for field changes and submit for review and approval to another "Services and Special projects" IP .

The "Site Manager" shall stop installation and on-site assembling activities affected by field changes until the revised documents have been approved as described above.

The Integrated Project Schedule (IPS) (See Section 07 of this Manual) for on-site activities shall be issued by "Site Manager" and maintained updated. Other specific documents should be used according to customer requirements.

19.3.4. Specifications, Procedures and Drawings

All specifications, procedures and drawings shall be prepared, according to [Sections 05](#) and [06](#) of this Manual.

19.3.5. Document Control

Document control shall be performed according to [Section 07](#) of this Manual; however it is permitted the use of hard copies of applicable documents on site.

"Site Manager" shall provide all specifications, procedures and drawings to the personnel responsible for carrying out the work. A record of distributed documents shall be maintained by "Site Manager".

"Site Quality Inspector" shall be responsible for verifying the use of approved and up-to-date documents by means of the Ensa intranet or PLM. "Site Quality Inspector" shall also be responsible for the withdrawal and destruction of obsolete revisions of the documents.

19.3.6. Control of Purchased Materials, Items and Services

All procurement activities are performed according to this Manual [Section 08](#) provisions, except for receiving inspection on-site, which shall be performed by Site Quality Inspector following this Manual [Section 08](#) requirements.

19.3.6.1. Customer Supplied Materials

In the case of Parts being manufactured/assembled by Ensa, material may be supplied by the Customer, who final responsibility for the component being has constructed either shipped directly from a material organization or the Customer.



The material is examined for shipping damage and identification by "Site Quality Inspector" and reported on a Material Receiving Notice (MR).

QAS shall review the release documentation showing the Customer's acceptance of the material and related CMTR and "Site Quality Inspector" verify the marking of the material for correctness and traceability to the documentation. Acceptance is indicated on a Receiving Inspection Report (IR/SR). Non conforming material shall be handled in accordance with [Section 15](#) of this Manual and the Customer notified immediately.

In the event that Ensa intranet is not accessible, "Site Quality Inspector" may indicate the approval of the material documentation at the field operation IPP according with the requirements of this Section.

19.3.6.2. Identification and Control of Materials and items

Same requirements of [Section 08](#) of this Manual shall apply.

19.3.7. Control of Construction Processes, Examinations, Tests and Inspections

Construction processes are controlled employing the IPP/HR (see Section 09 of this Manual). "Methods Engineer" or "Services and Special projects" IP prepares the work process where the IPP is obtained and will be documented with [Exhibit 09.18](#). "Methods Engineer" or "Services and Special projects" IP prepares the IPP and QAE, QAS or "Site Quality Inspector" approves and submit it to the ANI and/or Customer, TPI, NB or Regulatory Bodies for selection of his witness, review and hold points.

Qualification of personnel and procedures to be employed on-site, shall be performed as per Sections 02, 10, 11 and 12 of this Manual.

"Site Quality Inspector" shall be responsible for:

- Controlling the progress of the inspection sequence, assuring that the ANI, Customer, TPI, NB can witness the selected hold points.
- Signing for acceptance records and certificates of all the inspections they witness or perform with satisfactory results.

19.3.8. Welding

The same requirements as per [Section 10](#) of this Manual shall apply, modified as follows:

"Site Quality Inspector" shall be responsible for:

- Controlling the up-to-date qualification of the welders during field operations.
- Verification of the filler material identification and welding gases prior to welding operations.
- Surveillance welding operations according to applicable WPS and record welding parameters in Welding Records (WR).

"Site Manager" shall be responsible for:

FIELD OPERATIONSSECTION **19**

- Provide appropriate protection to adverse conditions.
- Controlling the correct filler material storage.
- Provide welding gases and welding material according to WPS requirements.

"Welding Engineer" shall be responsible for verification of welder qualifications and their maintenance in the welder qualification list.

19.3.9. Heat Treatment

The same requirements as per Section 05, 08 and 11 of this Manual shall apply, modified as required by on site conditions and indicated in on site addenda.

19.3.10. Non destructive Examination

The same requirements as per [Section 12](#) of this Manual shall apply, modified as required by on site conditions and indicated in on site addenda.

19.3.11. Handling, Storage, Shipping and Preservation

The same requirements as per [Section 13](#) of this Manual shall apply, modified as required by on site conditions and indicated in on site addenda. "Site Quality Inspector" shall be responsible for verifying that all items are correctly stored and preserved.

19.3.12. Control of Measuring and Test Equipment

The same requirements as per [Section 14](#) of this Manual shall apply. "Site Quality Inspector" shall verify the calibrated equipment to be used on-site.

"Site Quality Inspector" shall send the equipment back to "Metrology" unit for calibration or "Metrology technicians" goes to the site. Subcontracted calibration services may be used according to [Section 8](#).

"Site Quality Inspector" shall be responsible for checking that only calibrated equipment is used and maintaining a list of calibrated devices up-to-date.

19.3.13. Control of Non conformities

The same requirements as per [Section 15](#) of this Manual shall apply.

Affected item is tagged and a NCR is generated by "Site Quality Inspector". A disposition will be proposed and approved by IP. Submittal to Customer and ANI/TPI/NB or Regulatory Bodies for acceptance and selection of hold points is performed.

After verification of the disposition, the "Site Quality Inspector" will close the NCR by signature and date.

19.3.14. Audits and Corrective Actions

Independent auditing of activities at each site to verify the implementation of the Ensa



FIELD OPERATIONS

SECTION **19**

Quality Program as per [Section 17](#) of this Manual.

Auditing and qualifying field operations subcontractors, as per [Section 08](#) of this Manual.

Requiring corrective actions and verifying their implementation, as per [Section 16](#) of this Manual.

19.3.15. Quality Records

The same requirements of [Section 18](#) of this Manual shall apply, modified as required by on site conditions.

"Site Quality Inspector" shall forward all records, reports, certificates and other documents including the Lifetime Records Data Package.

All activities performed by Ensa on-site shall be documented through the same forms as used in Ensa plant, except when modified by the specific Site Addenda.

RT films shall be filed and stored in suitable conditions on site or in alternate locations.

19.3.16. -Reserved-

19.3.17. -Reserved-



PROCESS MAP

SECTION **20**

20.0 PURPOSE

20.1 PROCEDURE

20.2 PROCESS MAP



PROCESS MAP

SECTION **20**

20.0. PURPOSE

To enable the development of activities concerning this quality manual a series of processes and different activities linked one another are defined so that the transformation of items into results can be achieved

20.1. PROCEDURE

Quality Assurance makes the follow-up and process measurement through indicators which are analysed at the periodical reporting documents as described in Section 1.

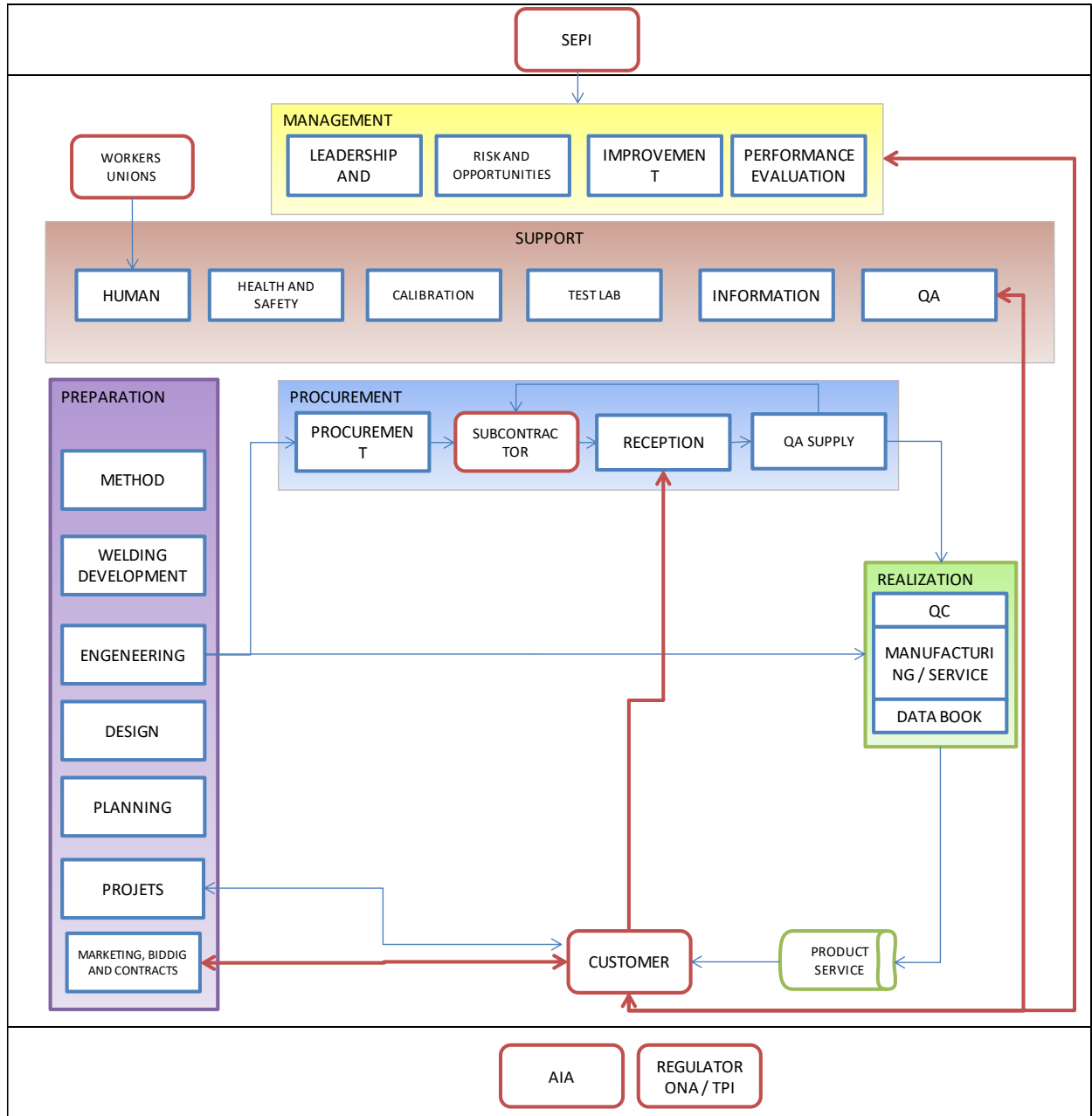
In case an anomaly occurs during the development of such processes, the necessary actions will be implemented to achieve the programmed results and the continuous improvement of the processes.

Process description sheet is managed through [Exhibit 04.03](#).

PROCESS MAP

SECTION **20**

20.2. PROCESS MAP





Implementación de UNE 73401

21.0 OBJETO

21.1 PROCEDIMIENTO

REFERENCES

Nota: Esta sección esta únicamente en Español.

Implementación de UNE 73401

SECTION 21

21.1 OBJETO

Definir la implementación de los requisitos definidos en la norma UNE 73401:1995 en el Manual de Garantía de Calidad de Ensa según requerido por distintas instrucciones y guías del Consejo de Seguridad Nuclear Español:

- Instrucción IS-12, de 28 de febrero de 2007, del Consejo de Seguridad Nuclear, por la que se definen los requisitos de cualificación y formación del personal sin licencia, de plantilla y externo, en el ámbito de las centrales nucleares
- Instrucción IS-19, de 22 de octubre de 2008, del Consejo de Seguridad Nuclear, sobre los requisitos del sistema de gestión de las instalaciones nucleares
- Instrucción IS-20, de 28 de enero de 2009, del Consejo de Seguridad Nuclear, por la que se establecen los requisitos de seguridad relativos a contenedores de almacenamiento de combustible gastado
- Instrucción IS-24, de 19 de mayo de 2010, del Consejo de Seguridad Nuclear, por la que se regulan el archivo y los periodos de retención de los documentos y registros de las instalaciones nucleares
- GS 06-01 Garantía de calidad en el transporte de sustancias radiactivas
- GS 10-01 Revisión 2 - Guía básica de garantía de calidad para instalaciones nucleares
- GS 10-02 Revisión 1 - Sistema de documentación sometida a programas de garantía de calidad en instalaciones nucleares
- GS 10-03 Revisión 1 - Auditorías de garantía de calidad
- GS 10-06 Revisión 1 - Garantía de calidad en el diseño de instalaciones nucleares
- GS 10-09 Garantía de Calidad de las aplicaciones informáticas relacionadas con la seguridad de las instalaciones nucleares
- GS 10-10 Revisión 1 -Cualificación y certificación de personal que realiza ensayos no destructivos
- GS 10-13 Garantía de calidad para el desmantelamiento y clausura de instalaciones nucleares

21.1 PROCEDIMIENTO

En la tabla 1 de esta sección se define la correspondencia entre los requisitos establecidos en la norma UNE 73401 y su sistemática en el sistema de Garantía de Calidad de Ensa.

Las secciones del Manual de Garantía de Calidad están desarrolladas con mayor detalle en los Procedimientos Generales relativos a cada sección los cuales están numerados con relación a la sección del Manual de Garantía de Calidad al que pertenecen.

Los requisitos de calidad de formación según IS-12 definidos para la cualificación de personal que realiza actividades de calidad se describen en la sección 2 y 12 del Manual de Garantía de Ensa. Para la cualificación y certificación de personal de Ensayos No Destructivos se considera la normativa ISO 9712. En caso de fabricación según ASME se podrá requerir además SNT TC 1 A.



Implementación de UNE 73401

La IS-24 se encuentra reflejada en la sección 18 del Manual de Garantía de Calidad considerando que para los contratos en los que aplica la norma UNE 73401 el periodo mínimo de retención de los registros no permanentes es de 5 años.

Por otra parte, los requisitos de GS 10.3 "Auditorias de garantía de calidad" se encuentra recogida en la sección 18.

En el caso particular de las subcontrataciones, en aquellos casos que las subcontrataciones sean complejas y el cliente así lo requiere, éstas se le notificarán por escrito preferiblemente vía IPS (Integrated Planning Schedule).

La actualización del Sistema de Garantía de Calidad se realiza mediante la participación en foros de calidad como los organizados por la SNE, formaciones específicas sobre códigos y normativas nucleares, revisión de nuevas ediciones de normativa aplicable, etc..

REFERENCIAS

- Norma UNE 73401:1995
- <https://www.csn.es/instrucciones-tecnicas-is->
- <https://www.csn.es/guias-de-seguridad>

Implementación de UNE 73401

SECTION **21**

Tabla 1: **Correspondencia entre UNE 73 401 y Manual de Calidad Ensa**

TABLA DE CUMPLIMIENTO		
UNE 73 401	QM-ISO Sección	OBSERVACIONES
2. Idioma	2	
3. Responsabilidades	1	
5.1 Programa de Garantía de Calidad.	1 y 2	
5.2 Organización.	3	
5.3 Control de Diseño.	5	
5.4 Control de documentos de compra.	8	
5.5 Instrucciones, procedimientos y representaciones gráficas.	6	
5.6 Control de documentos.	7	
5.7 Control de equipos y servicios adquiridos.	8	
5.8 Identificación y control de elementos.	8 y 9	
5.9 Control de procesos.	9 10 11 12	Soldadura Tratamiento Térmico Control de END
5.10 Inspección y supervisión.	9	
5.11 Control de pruebas.	9	
5.12 Control de equipos de medida y prueba.	14	
5.13 Manipulación, almacenamiento y expedición.	13	
5.14 Estado de las inspecciones, pruebas y operación.	9	
5.15 Control de desviaciones.	15	
5.16 Acciones correctoras.	16	
5.17 Registros de Garantía de Calidad.	18	
5.18 Auditorías.	17	



EQUIPOS NUCLEARES, S.A., S.M.E.
QUALITY ASSURANCE MANUAL

QM-ISO Rev.15

----- END OF DOCUMENT-----